[] Feet Shoet 524-5-75 1/09

524-575





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Poliution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE REGISTRATION

X Registration Reregistration

(under FIFRA, as amended)

Name	and Add	iress of	Registi	rant (ind	lude ZIP	Code):

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the jabel in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under ' 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

- 1) The subject registration will automatically expire on midnight September 30, 2010.
- 2) The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn may not be sold to small roadside or home growers.
- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.

Signature of Approving Official:

Janet Andersen, Ph.D., Director

Biopesticides and Pollution Prevention Division (7511P)

oate:

EPA Reg.

Number: 524-575

Term of

issuance:

Name of Pesticide Product:

Oate of Issuance:

Conditional

Time-Limited

MON 89034

6/18/08

EPA Form 8570-6

EPA Reg. Number: 524-575 Term of Time- Limited Issuance: Name of Pesticide Product: U.S. ENVIRONMENTAL PROTECTION AGENCY MON 89034 Office of Pesticide Programs Biopesticides and Pollution Prevention Division (7511P) 1200 Pennsylvania Avenue NW Washington, DC 20460 NOTICE OF PESTICIDE REGISTRATION X Registration Reregistration (under FIFRA, as amended) Name and Address of Registrant (include ZIP Code): Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Bjopest(cides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number. On the basis of information furnished by the registrant, the above named pesticide is nereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others. The registration application referred to above, submitted in connection with registration under '3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions. The subject registration will automatically expire on midnight September 30, 2010. The subject registration will be limited to MON 89034 in field or sweet corn. Further, MON 89034 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 sweet corn may not be sold to small roadside or home growers 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data. Signature of Adproving Official: 6/10/08 Janet Andersen, Ph.D., Director Biopesticides and Pollution Prevention Division (Revotes) SYMBOL

EPA Form 1320-1A (1/90)

SURNAME]

DATE

Printed on Recycled Paper

OFFICIAL FILE COPY

4) Submit the following data in the time frames listed:

OPPTS Guideline/ Study Type	Required Data	Due Date
860.1340 Residue Analytical method - Plants	For event MON 89034 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105. The registrant must also agree to provide to the EPA laboratory (Ft. Meade, MD) methodology and/or reagents necessary for validation of such analytical method within 6 months from the date that the Agency requests them.	4/1/2009
850.1010 Aquatic Invertebrate Acute Toxicity Testing, Freshwater Daphnids	A 7 to 14 day <i>Daphnia</i> study as per the 885 Series OPPTS Guidelines needs to be performed. Alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams, can be performed and submitted in lieu of the <i>Daphnia</i> study.	4/1/2009
Insect Resistance Management	Monsanto did not address the likelihood of cross-resistance of Cry1A. t05, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A. t05 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.	4/1/2009 Protocol Due 8/1/2008
Insect Resistance Management	Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.	4/1/2009 Protocol Due 8/1/2008
Insect Resistance Management	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.	4/1/2009

OPPTS Guideline/ Study Type	Required Data	Due Date
Insect Resistance Management	To support sweet corn uses, baseline susceptibility studies must be conducted on FAW populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

 The registrant must do the following Insect Resistance Management Program for MON 89034.

a) Refuge Requirements for MON 89034.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 89034] field. Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4 consecutive rows wide. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

b) Grower Agreements for MON 89034.

- Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.



- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.
- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034.

i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other



- organizations, such as the National Corn Growers Association and state extension programs.
- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv.) below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. xv.) below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the Monsanto corn PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto corn PIP products.
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.



- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs vi. through viii. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This onfarm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.



d) Insect Resistance Monitoring for MON 89034.

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1.A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for **c**orn rootworm.
- iv. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests.

The annual reporting requirements are as follows:

 Annual Sales: reported and summed by state (county level data available by request), January 31st each year;



- ii. Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, August 31st each year.

A stamped copy of the label is enclosed for your records.

Regards,

Janet Andersen, Ph.D.

Director

Biopesticides and Pollution

Prevention Division

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn (OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS____

EPA Registration No. 524-575

EPA Establishment No. 524-MO-002

ACCEPTED

JUN 1 0 2008

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 524-575

Monsanto Company 800 North Lindbergh Blvd. St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

MON 89034 can be crossed with MON 88017 for breeding purposes to produce MON 89034 x MON 88017

In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

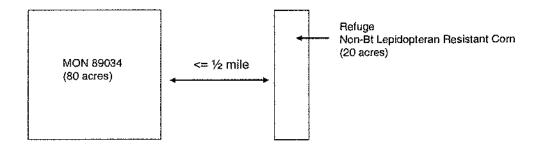
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plowdown within one (1) month of harvest.

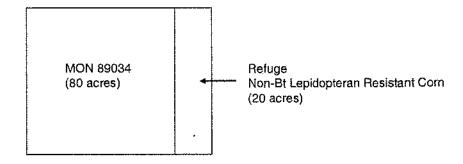
For MON 89034 field corn, grower guides must specify that growers must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 rows wide.



Insecticide treatments for control of European corn borer, corn earworm, and Southwestern corn borer, cornstalk borer, sugarcane borer, fall armyworm and stalk borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn Insects Controlled

European corn borer Southwestern corn borer Southern cornstalk borer Corn earworm Fall armyworm Corn stalk borer Sugarcane borer Ostrinia nubilalis Diatraea grandiosella Diatraea crambidoides Helicoverpa zea Spodoptera frugiperda Papaipema nebris Diatreae saccharalis

Sales of corn hybrids that contain Monsanto's Bt corn plant-incorporated protectant must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.

Monsanto Company 06-CR-172E-2 Page 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY - 6 2008

OPP Decision Numbers:

D-371189

D-37t190

Yong Gao Regulatory Affairs Manager Monsanto Company 1300 I Street, NW Suite 450 East Washington, DC 20005

Subject: Pre-Acceptance Letter for: MON 89034 (Cry1A.105 and Cry2Ab2) and

MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn

EPA Petition Numbers: 6F7142 and 6F7143

EPA File Symbols: 524-LTA, 524-LTL Application Date: September 29, 2006 EPA Receipt Date: September 29, 2006

Dear Dr. Gao:

This is a pre-acceptance letter regarding Monsanto Company's applications to register the above referenced products for Section 3 registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider registering Monsanto Company's products under FIFRA Section 3(c)(7)(C) provided Monsanto Company amends its applications for registration by submitting the required information as described in this letter.

This letter does not constitute a commitment to register the subject product, nor is it intended to imply that EPA will register the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto Company submits the information in writing as described in this letter, EPA will be able to continue to process the registration application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that Monsanto Company agrees in writing to the following.

 The subject registrations will automatically expire on midnight September 30, 2010.

2) The subject registrations wild us firmited to MON 89034 and MON 89034 x MON									
SYMBOL -	7511 Pm	88	3017 in	field or sweet	corn. Further	MON 8 9 034	and MON 890	34 x MON	
SURNAME >	evel	75	(1)						
DATE 5	-C-08	Rul	1				:: 		_ (14)
EPA Form 1320	-1A (1/90)	5/6	08	P	rinted on Recycled	Paper		OFFIC	IAL FILE COPY

88017 sweet corn may only be sold directly to processors or through commercial dealers to large growers. MON 89034 and MON 89034 x MON 88017 sweet corn may not be sold to small roadside or home growers

- 3) Submit/cite all data required for registration of your product under FIFRA §3(c)(5) when the Agency requires registrants of similar products to submit such data.
- 4) Submit the following data in the time frames listed:

Data Required to Support Both MON 89034 and MON 89034 x MON 88017

ODDTC Cuidoling/Study	I Domileod Dota	Due Date
OPPTS Guideline/ Study	Required Data	Due Date
Type		4/4/0000
860.1340 Residue	For event MON 89034 corn and event MON	4/1/2009
Analytical method -	89034 x MON 88017 corn, an independent lab	
Plants	validation of the analytical method for the	<u> </u>
	detection of Cry2Ab2 and/or Cry1A.105. You	
	must also agree to provide to the EPA laboratory	
1	(Ft. Meade, MD) methodology and/or reagents	
	necessary for validation of such analytical	
	method within 6 months from the date that the	
<u> </u>	Agency requests them.	
850.1010 Aquatic	A 21 day daphnia study, as outlined in the	4/1/2009
Invertebrate Acute	OPPTS Microbial Test Guidelines, needs to be	
Toxicity Testing,	performed for MON 89034	
Freshwater Daphnids		444/0000
Insect Resistance	Monsanto did not address the likelihood of cross-	4/1/2009
Management	resistance of CrytA.105, Cry1Ac, Cry1Fa,	
	proteins already in existing Bt corn and Bt cotton	Protocol Due
	products, and what impact such cross-resistance	8/1/2008
	would have on the durability of MON 89034.	
**	Monsanto must provide additional information on	,
	cross-resistance of Cry1A.105 and Cry1Fa and	
	Cry1Ac (preferably including binding site models	
	and use of resistant colonies) for the target pests	
	and determine how such cross-resistance may	
	impact the durability of MON 89034. The	
Ļ	Cry1A.105 protein is a chimeric protein	
•	consisting of Domains I and II and the C-terminus	
	of Cry1Ac and Domain III of Cry1Fa. It is	
	important to address not only the likelihood of	
·	cross-resistance potential of Cry tA. 105 and	
	Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2	1
	(which was done by Monsanto), but also that of	
	Cry1A. t05 and Cry1Ac and CrytFa.	

Insect Resistance Management	Monsanto did not sufficiently address the cross- resistance of Cry1A.105, Cry1Fa, and Cry1Ac in	4/1/2009
	the cotton-growing landscape and how cross- resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.	Protocol Due 8/1/2008
Insect Resistance Management	Baseline susceptibility studies and/or a discriminating concentration assay are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.	4/1/2009
Insect Resistance Management	To support sweet corn uses, baseline susceptibility studies must be conducted on FAW populations collected from sweet corn growing areas. Monitoring studies will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres. The collected populations of FAW will be monitored for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.	4/1/2010

Additional Data Required to Support MON 89034 and MON 89034 x MON 88017

- 5) Submit or cite all data required to support the individual plant-incorporated protectant in Event MON863 (YieldGard Rootworm), 524-528. In the event that the Agency concludes MON 863 (YieldGard Rootworm) studies do not sufficiently demonstrate a lack of significant adverse effects, additional data with MON 88017 corn must be submitted. This data may include a) laboratory toxicity testing with *Orius insidiosus* (minute pirate bug), b) laboratory toxicity testing with a carabid (ground beetle), c) long range effects testing on invertebrate populations in the field, and d) long range soil persistence testing.
- 6) Apply to amend the MON 88017 registration to allow the breeding use to produce MON $88017 \times MON$ 89034.
- 7) You must commit to do the following Insect Resistance Management Program for MON 89034.



a) Refuge Requirements for MON 89034.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

The corn borer refuge must be planted with a non-Bt/lepidopteran-protected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 89034] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. Growers who fail to comply with the IRM requirements risk losing access to Monsanto PIP products.

b) Grower Agreements for MON 89034.

- Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.
- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a

- proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034.

- i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.
- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.



- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv.) below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034. Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034. Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. xv.) below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the Monsanto PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto PIP products.
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.
- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.

- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs vi. through viii. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints, grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the

State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034.

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1.A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for *Spodoptera frugiperda* (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- iv. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests.

The annual reporting requirements are as follows:

- Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- v. Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, April 30th each year.
- 8) You must commit to do the following Insect Resistance Management Program for MON 89034 x MON 880 t7.

a) Refuge Requirements for MON 89034 x MON 88017

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn nor to commercial hybrid sweet corn.

Grower agreements (also known as stewardship agreements) will specify that growers must adhere to the following refuge requirements or, in the case of sweet corn, harvest practices as described in the grower guide/product use guide and/or in supplements to the grower guide/product use guide.

For MON 89034 x MON 88017 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plow-down within one (1) month of harvest.

Two options for deployment of the refuge are available to growers. The first option is planting a common refuge for both corn borers and corn rootworms. The common refuge must be planted with corn hybrids that do not contain Bt technologies for the control of corn rootworms or corn borers. The refuge area must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and refuge acres). It can be planted as a block adjacent to the [MON 88017 x MON 89034] field, perimeter strips, or in-field strips. If perimeter strips are implemented, the strips must be at least 4, and preferably 6

consecutive rows wide. If strips within the [MON 88017 x MON 89034] field are implemented, then at least 4, and preferably 6 consecutive rows should be planted. The common refuge can be treated with a soil-applied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests if pest pressure reaches an economic threshold for damage; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner.

The second option is planting separate refuge areas for corn borers and corn rootworms. The corn borer refuge must be planted with a non-Bt/lepidopteranprotected hybrid, must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn borer refuge acres), and must be planted within ½ mile of the [MON 88017 x MON 89034] field. The corn borer refuge can be treated with a soil-applied or seed-applied insecticide for corn rootworm larval control, or a non-Bt foliar-applied insecticide for corn borer control if pest pressure reaches an economic threshold for damage. The corn rootworm refuge must be planted with a non-Bt/corn rootworm-protected hybrid, but can be planted with Bt corn hybrids that control corn borers. The corn rootworm refuge must represent at least 20% of the grower's corn acres (i.e. sum of [MON 88017 x MON 89034] acres and corn rootworm refuge acres) and can be planted as an adjacent block, perimeter strips, or in-field strips. The corn rootworm refuge can be treated with a soilapplied or seed-applied insecticide to control rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt foliar insecticide for control of late season pests; however, if rootworm adults are present at the time of foliar applications then the [MON 88017 x MON 89034] field must be treated in a similar manner. Growers who fail to comply with the IRM requirements risk losing access to Monsanto PIP products.

b) Grower Agreements for MON 89034 x MON 88017

- i. Persons purchasing the Bt corn product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- ii. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- iii. The registrant must integrate this registration into the current system used for their other Bt corn PIPS to reasonably likely to assure that persons purchasing the Bt corn product will affirm annually that they are contractually bound to comply with the requirements of the IRM program. A description must be submitted to EPA by August 1, 2008.

33

- iv. The registrant must use grower agreements and submit to EPA within 90 days from the date of registration a copy of that agreement and any specific stewardship documents referenced in the grower agreement. If Monsanto wishes to change any part of the grower agreement or any specific stewardship documents referenced in the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, the registrant must submit to EPA the text of such changes to ensure that it is consistent with the terms and conditions of the amendment.
- v. The registrant must integrate this registration into the current system to assure that persons purchasing the Bt corn sign grower agreement(s), and must provide within 90 days from the date of the registration a written description of that system. A description must be submitted to EPA by August 1, 2008.
- vi. The registrant shall maintain records of all Bt corn grower agreements for a period of three years from December 31st of the year in which the agreement was signed.
- vii. Beginning on January 31, 2010 and annually thereafter, the registrant shall provide EPA with a report showing the number of units of its Bt MON 89034 x MON 88017 corn seeds sold or shipped and not returned, and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve month period covering the prior August through July.
- viii. The registrant must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

c) IRM Education and IRM Compliance Monitoring Programs for MON 89034 x MON 88017

i. Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bt MON 89034 x MON 88017 corn users the importance of complying with the IRM program. The program shall include information encouraging Bt MON 89034 x MON 88017 corn users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bt MON 89034 x MON 88017 corn fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, EPA reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by Internet, radio, or television commercials. Copies of the materials will be provided to EPA for its records. The program shall involve at least one written communication annually to each Bt MON 89034 x MON 88017 corn user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements. Monsanto shall coordinate its education programs with educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.



- ii. Annually, the registrant shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph vi. and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
- iii. On January 31, 2010, the registrant must provide a report to EPA summarizing the activities carried out under the education program for the prior year. Annually thereafter, the registrant must provide EPA any substantive changes to its grower education activities as part of the overall IRM compliance assurance program report. The required features of the compliance assurance program are described in paragraphs iv.-xv. below.
- iv. The registrant must design and implement an ongoing IRM compliance assurance program designed to evaluate the extent to which growers purchasing its MON 89034 x MON 88017 Bt corn product are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the MON 89034 x MON 88017 Bt corn product. The registrant shall coordinate with other Bt corn registrants in designing and implementing its compliance assurance program and integrate this registration into the current compliance assurance program used for their other Bt corn PIPS. The registrant must prepare and submit within 90 days of the date of registration a written description of their compliance assurance program. Other required features of the program are described in paragraphs v. xv. below.
- v. The registrant must establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how the registrant will address instances of noncompliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bt corn for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of Monsanto PIP products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell Monsanto PIP products
- vi. The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bt corn growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. The sample size and geographical resolution may be adjusted annually, based upon input from the independent marketing research firm and academic scientists, to allow analysis of compliance behavior within regions or between regions. The sample size must provide a reasonable sensitivity for comparing results across the U.S. The survey will include only growers planting at

- least 200 acres of corn in the Corn Belt or 100 acres of corn in corn/cotton growing regions.
- vii. The survey shall be designed to provide an understanding of any difficulties growers encounter in implementing IRM requirements. An analysis of the survey results must include the reasons, extent, and potential biological significance of any implementation deviations.
- viii. The survey shall be designed to obtain grower feedback on the usefulness of specific educational tools and initiatives.
- ix. The registrant shall provide a final written summary of the results of the prior year's survey (together with a description of the regions, the methodology used, and the supporting data) to EPA by January 31 of each year. The registrant shall confer with EPA on the design and content of the survey prior to its implementation.
- x. Annually, the registrant shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraphs 6] through 8] and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. The registrant must confer with the Agency prior to adopting any changes to a previously approved CAP.
- xi. The registrant shall train its representatives who make on-farm visits with MON89034 x MON 88017 Bt corn growers to perform assessments of compliance with IRM requirements. In the event that any of these visits result in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach," to promote compliance. This on-farm assessment program has no minimum acreage threshold for growers.
- xii. The registrant shall carry out a program for investigating legitimate "tips and complaints" that its growers are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, the registrant shall take appropriate action, consistent with its "phased compliance approach."
- xiii. If a grower, who purchases MON 89034 x MON 88017 Bt corn for planting, was specifically identified as not being in compliance during the previous year, the registrant shall visit with the grower and evaluate whether that the grower is in compliance with the IRM program for the current year.
- xiv. Beginning January 31, 2010 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities carried out under their compliance assurance program for the prior year and the plans for the compliance assurance program during the current year. The report will include information regarding grower interactions (including, but not limited to, on-farm visits, verified tips and complaints,



- grower meetings and letters), the extent of non-compliance, corrective measures to address the non-compliance, and any follow-up actions taken.
- xv. The registrant and the seed corn dealers for the registrant must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including the names, personal information, and grower license number of the growers will be protected.

d) Insect Resistance Monitoring for MON 89034 x MON 88017

The Agency is imposing the following conditions for this product:

- i. Post-commercial resistance monitoring programs must be established as an extension of existing programs to track the susceptibility of the key lepidopteran corn pests to the Cry1A.105 and Cry2Ab2 proteins. For the Cry1.A.105 and Cry2Ab2 proteins, the registrant will monitor for resistance and/or trends in increased tolerance for European corn borer, Southwestern corn borer, and corn earworm. Sampling should be focused in those areas in which there is the highest risk of resistance development. Monitoring must be carried out under the same protocols used for the products containing MON 810. Sampling should be focused in those areas in which there is the highest risk of resistance development. In the monitoring program, insect populations will be collected and each protein will be tested separately, rather than a mixture of the two proteins, because resistance to one protein could be masked by the activity of the other.
- ii. In addition to monitoring ECB, SWCB, and CEW, Monsanto will develop and ensure the implementation for resistance monitoring for Spodoptera frugiperda (fall armyworm of FAW) in counties which MON 89034 / MON 89034 x MON 88017 sweet corn acreage exceeds 5,000 acres and the pest is capable of overwintering in that county. The registrant should consult with academic and USDA experts in developing the monitoring plan and will provide EPA with a copy of its proposed resistance monitoring plan for EPA's approval prior to implementation. This proposed FAW monitoring plan must be submitted to EPA by January 31 of the year following that in which MON 89034/ MON 89034 x MON 88017 sweet corn acreage exceeds the trigger specified in this requirement (i.e., greater than 5,000 acres in any county in which FAW overwinters). The proposed plan must be implemented the season following the acreage trigger being met. The proposed plan will remain in place until an EPA approved plan can be implemented.
- iii. For the Cry3Bb1 portion of the product, a revised Cry3Bb1 monitoring plan that incorporates MON 89034 x MON 88017 must be submitted to the Agency within 90 days of the date of registration.
- iv. For the Cry3Bb1 portion of the product, the registrant must develop and validate an appropriate discriminating or diagnostic dose assay by January 31, 2010.

- v. For the Cry3Bb1 portion of the product, the registrant must finalize rootworm damage guidelines and submit these to BPPD by January 31, 2010.
- vi. The registrant must follow-up on grower, extension specialist or consultant reports of unexpected damage or control failures for corn rootworm.
- vii. The registrant must provide EPA with an annual resistance monitoring report by August 31st of each year beginning with 2010, reporting on populations collected the previous year.

e) Remedial Action Plans for MON 89034 x MON 88017

The October 15, 2001 Remedial Action Plan for Responding to Resistance in European Corn Borer, Corn Earworm and/or Southwestern Corn Borer must be used for suspected and confirmed resistance of these pests. The current remedial action plan approved for MON 863 must be used for corn rootworm suspected and confirmed resistance in [MON 89034 x MON 88017]. If corn rootworm resistance is confirmed, all acres ([MON 889034 x MON 88017] and refuges) must be treated with insecticides targeted at CRW adults as well as larvae.

The annual reporting requirements are as follows:

- Annual Sales: reported and summed by state (county level data available by request), January 31st each year;
- ii. Grower Agreement: number of units of Bt corn seeds shipped or sold and not returned, and the number of such units that were sold to persons who have signed grower agreements, January 31st each year;
- iii. Grower Education: substantive changes to education program completed previous year, January 31st each year;
- iv. Compliance Assurance Plan: Compliance Assurance Program activities and results, January 31st each year;
- Compliance: to include annual survey results and plans for the next year; full report January 31st each year;
- vi. Insect Resistance Monitoring Results; results of monitoring and investigations of damage reports. April 30th each year.

Label and Administrative Materials:

You must submit an updated label, Confidential Statement of Formula (CSF), Certification with Respect to Citation of Data form, and data matrix for both products. The labels must list separately those pests that are controlled and those that are suppressed as well as the IRM refuge and harvest requirements. The data matrix and Certification with Respect to Citation



of Data form should have the same date. Each of the CSFs and labels should have the same product name and be based on actual expression level data. You must also formally address all the requirements listed in 40 CFR Part 158.740, e.g. via waiver requests where appropriate. The updated label should include modifications to the IRM requirements listed in this letter.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto Company submits the information in writing as described in this letter, however, EPA will be able to continue to process the registration application.

Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,

Sheryl K, Reilly, Ph.D. Chief Microbial Pesticide Branch Biopesticides and Pollution Prevention Division (7511P)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Washington, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

JUN 0 9 2000

MEMORANDUM

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Time-Limited Registration for

Monsanto's Plant-incorporated Protectants, Bacillus thuringiensis Cryl A.105 and

Cry2Ab2 Insecticidal Protein and the Genetic Material Necessary for Their

Production in MON 89034 Corn

(EPA File Symbols 524-LTA and 524-LTL) -DECISION MEMORANDUM

FROM:

Janet L. Andersen, Ph.D., Director

Biopesticides and Pollution Prevention Division

TO:

Debra Edwards, Ph.D., Director

Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register the subject pesticides until September 30, 2010 pursuant to FIFRA §3(c)(7)(C)?

II. RATIONALE FOR RECOMMENDATION

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of new active ingredients if it is determined that 1) use of the pesticide during a defined period of time will not cause any unreasonable adverse effect on the environment; 2) use of the pesticide is in the public interest; and 3) that for the data that is lacking, a reasonable period of time sufficient for generation of the data has not elapsed since the Agency first imposed the data requirements.

To satisfy criterion (1) above, we have determined that this plant-incorporated protectant pesticide will not cause any unreasonable adverse effects on human health or the environment.

The data have been reviewed and BPPD has determined that a section 3(c)(7)(C) conditional registration that is limited in duration is appropriate in this situation. Data requirements for granting the subject time-limited registrations for use of these products under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been met. BPPD has determined that these products will cause no unreasonable adverse effects to the environment if used in compliance with the terms and conditions of registration, as presented in the Biopesticide

registrations. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

The expiration date of the registrations has been set to September 30, 2010.

CONCUR: NON-CONCUR:	

DATE: 6/9/08 Weller Elwan 12

Registration Action Document (BRAD) for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal protein and the genetic material necessary for their production in MON 89034 corn.

III. RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking if insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

Insufficient time has elapsed since the initial imposition of the data requirements for:

- 1) An independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 to satisfy residue analytical method in plants requirements for event MON 89034 corn and event MON 89034 x MON 88017 corn.
- 2) A 7 to 14 day *Daphnia* study as per the 885 Series OPPTS Guidelines or, alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams.
- 3) Additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determination of how such cross-resistance may impact the durability of MON 89034.
- 4) Baseline susceptibility studies and/or a discriminating concentration assay that are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.
- 5) Baseline susceptibility studies to support sweet corn uses that must be conducted on FAW populations collected from sweet corn growing areas; monitoring studies that will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres; and monitoring of the collected populations of FAW for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.



The applicants submitted or cited data sufficient for EPA to determine that conditional registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment. The applicants submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and nontarget organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to Cry2Ab2 and Cry 1A.105 proteins, during the conditional registrations, is not expected to be significant.

Registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn is in the public interest because:

(1) Registration of MON 89034 is expected to result in the reduction of the use of higher risk, and often less effective and more expensive, conventional pesticides. A reduction in use of conventional pesticides equates to less potential for adverse effects to human health and the environment.

)

(2) Additionally, MON 89034 provide a wider spectrum of protection against primary and secondary corn pests, which should facilitate greater grain quality, a reduction of mycotoxin contamination, increased yield and ultimately, positive implications for human health.

In view of these minimal risks and the clear benefits related to *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn, EPA believes that the use of these products during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified in Section III of the BRAD.

EPA has determined, as explained in the Benefits and Public Interest Finding Assessment, that the use of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under these registrations are in the public interest.

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of these

JUN 0 9 2008

<u>MEMORANDUM</u>

SUBJECT: Consideration of Section 3(c)(7)(C) Conditional Time-Limited Registration for

Monsanto's Plant-incorporated Protectants, Bacillus thuringiensis CrylA.105 and

Cry2Ab2 Insecticidal Protein and the Genetic Material Necessary for Their

Production in MON 89034 Corn

(EPA File Symbols 524-LTA and 524-LTL) -DECISION MEMORANDUM

FROM:

Janet L. Andersen, Ph.D., Director

Biopesticides and Pollution Prevention Division

TO:

Debra Edwards, Ph.D., Director

Office of Pesticide Programs

I. ISSUE

Should the Agency conditionally register the subject pesticides until September 30, 2010 pursuant to FIFRA §3(c)(7)(C)?

II. RATIONALE FOR RECOMMENDATION

Section 3(c)(7)(C) of FIFRA provides for the conditional registration of new active ingredients if it is determined that 1) use of the pesticide during a defined period of time will not cause any unreasonable adverse effect on the environment; 2) use of the pesticide is in the public interest; and 3) that for the data that is lacking, a reasonable period of time sufficient for generation of the data has not elapsed since the Agency first imposed the data requirements.

To satisfy criterion (1) above, we have determined that this plant-incorporated protectant pesticide will not cause any unreasonable adverse effects on human health or the environment.

The data have been reviewed and BPPD has determined that a section 3(c)(7)(C) conditional registration that is limited in duration is appropriate in this situation. Data requirements for granting the subject time-limited registrations for use of these products under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been met. BPPD has determined that these products will cause no unreasonable adverse effects to the environment if used in compliance with the terms and conditions of registration, as presented in the Biopesticide

	CONCURRENCES	
SYMBOL > 751P 750P	· .	
SURNAME Soul Rul		
DATE > 6/9/08 6/9/08		34)
EPA Form 1320-1A (1/90)	Printed on Recycled Paper	OFFICIAL FILE COPY

Registration Action Document (BRAD) for *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 insecticidal protein and the genetic material necessary for their production in MON 89034 corn.

III. RECOMMENDATION

Pursuant to FIFRA section 3(c)(7)(C), EPA may conditionally register a new pesticide active ingredient for a period of time reasonably sufficient for the generation and submission of required data that are lacking if insufficient time has elapsed since the imposition of the data requirement for those data to be developed. EPA may grant such conditional registration only if EPA determines that the use of the pesticide product during the period of the conditional registration will not cause any unreasonable adverse effect on the environment, and the registration and use of the pesticide during the conditional registration is in the public interest. EPA determines that all of these criteria have been fulfilled.

Insufficient time has elapsed since the initial imposition of the data requirements for:

- 1) An independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 to satisfy residue analytical method in plants requirements for event MON 89034 corn and event MON 89034 x MON 88017 corn.
- 2) A 7 to 14 day *Daphnia* study as per the 885 Series OPPTS Guidelines or, alternatively, a dietary study of the effects on an aquatic invertebrate, representing the functional group of a leaf shredder in headwater streams.
- 3) Additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determination of how such cross-resistance may impact the durability of MON 89034.
- 4) Baseline susceptibility studies and/or a discriminating concentration assay that are required for the Cry1A.105 protein against ECB, SWCB, and CEW and for the Cry2Ab2 protein against SWCB, CEW.
- 5) Baseline susceptibility studies to support sweet corn uses that must be conducted on FAW populations collected from sweet corn growing areas; monitoring studies that will be conducted on FAW populations collected from sweet corn distribution areas in states in which Monsanto MON 89034 and/or MON 89034 x MON 88017 sweet corn plantings exceed 1000 acres; and monitoring of the collected populations of FAW for changes in susceptibility to the Cry1A.105 and Cry2Ab2 proteins.

The applicants submitted or cited data sufficient for EPA to determine that conditional registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under FIFRA 3(c)(7)(C) will not result in unreasonable adverse effects to the environment. The applicants submitted and/or cited satisfactory data pertaining to the proposed use. The human health effects data and nontarget organism effects data are considered sufficient for the period of the conditional registration. These data demonstrate that no foreseeable human health hazards or ecological effects are likely to arise from the use of the product and that the risk of resistance developing to Cry2Ab2 and Cry 1A.105 proteins, during the conditional registrations, is not expected to be significant.

Registration of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn is in the public interest because:

- (1) Registration of MON 89034 is expected to result in the reduction of the use of higher risk, and often less effective and more expensive, conventional pesticides. A reduction in use of conventional pesticides equates to less potential for adverse effects to human health and the environment.
- (2) Additionally, MON 89034 provide a wider spectrum of protection against primary and secondary corn pests, which should facilitate greater grain quality, a reduction of mycotoxin contamination, increased yield and ultimately, positive implications for human health.

In view of these minimal risks and the clear benefits related to *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn, EPA believes that the use of these products during the limited period of the conditional registration will not cause any unreasonable adverse effects.

Although the data with respect to this particular new active ingredient are satisfactory, they are not sufficient to support an unconditional registration under FIFRA 3(c)(5). Additional data are necessary to evaluate the risk posed by the continued use of this product. Consequently, EPA is imposing the data requirements specified in Section III of the BRAD.

EPA has determined, as explained in the Benefits and Public Interest Finding Assessment, that the use of *Bacillus thuringiensis* Cry2Ab2 and Cry 1A.105 proteins and the genetic material necessary for their production in event MON 89034 field corn and sweet corn under these registrations are in the public interest.

The submitted data in support of this registration under section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) have been reviewed and determined to be adequate. Studies mentioned above are included in the terms, conditions, and limitations of these



registrations. This registration will not cause unreasonable adverse effects to man or the environment and is in the public interest.

The expiration date of the registrations has been set to September 30, 2010.

CONCUR: _____ NON-CONCUR: ____

DATE: 6/9/08 Delia dumels



Mike Mendelsohn/DC/USEPA /US 05/22/2008 03:t4 AM To Susanne Cerrelli/DC/USEPA/US@EPA

CC John Kough/DC/USEPA/US@EPA

bcc

Subject Fw: Latest version for EPA

Susanne,

FYI- This is an example of what Monsanto sent a few years ago to address the microbial data waivers. The eco section of the BRAD does address at least some waivers. I don't know if or how Monsanto submitted them.

Sorry about not getting the tolerance exemption piece - just not enough time. John probably has it taken care of already. My thought was to explain how most of the tox and allergenicity data was not developed based on the plant produced protein, but on the bacterially produced protein and on the sequence that was in the vector for the AA homology. On the analytical method, I thought we could say we have a method, but it was not needed because this is a tolerance exemption. Also on the glycosylation section, I thought adding basic information relative to the eucaryotic nature of glycosylation might help and that the Cry protein is a procaryotic protein.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
http://www.epa.gov/pesticides/biopesticides
----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/22/2008 03:05 AM ------

Mike

Mendelsohn/DC/USEPA

/US

05/t9/2008 07:51 AM

To Mike Mendelsohn/DC/USEPA/US@EPA

CC

Subject Fw: Latest version for EPA

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/19/2008 07:45 AM -----



"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@m onsanto.com>

To Mike Mendelsohn/DC/USEPA/US@EPA, Phil Hutton/DC/USEPA/US@EPA

CC

02/2 t/2003 09:04 AM

Subject FW: Latest version for EPA

Mike/Phil,



Sheryl Reilly/DC/USEPA/US 05/22/2008 10:01 AM

To Alan Reynolds/DC/USEPA/US@EPA, Jeannette Martinez/DC/USEPA/US@EPA, cerrelli.susanne@epa.gov

cc_mendelsohn.mike@epa.gov

bcc

Subject Fw: Background info for today's Conference call regarding proposed changes to IRM refuge plans

---- Forwarded by Sheryl Reilly/DC/USEPA/US on 05/22/2008 09:59 AM ----



"Lucy Reed"
<reedle@inspection.gc.
ca>
05/21/2008 04:05 PM

To Sheryl Reilly/DC/USEPA/US@EPA

cc "Tanya Fielding" <fieldingt@inspection.gc.ca>

Subject Re: Conference call regarding proposed changes to IRM refuge plans

Hi Sheryl,

Actually here's a bit of background for you and your group to consider for tomorrow's call.

In Canada, a condition of authorization for the unconfined environmental release of Bt corn is the implementation of an insect resistance management (IRM) plan; this condition is imposed to manage an identified risk. In Canada, there is one "generic" plan for corn resistant to the European Corn Borer (ECB) and one "generic" plan for those crops resistant to corn rootworm (CRW). A main component of both of these plans is the requirement for a 20% refuge to be planted.

Results from the 2007 Stratus Canadian phone survey regarding compliance with IRM plan requirements has indicated that compliance with the 20% refuge requirement has decreased relative to the 2005 and 2003 phone surveys. As a result, the Canadian Food Inspection Agency (CFIA) is planning to host a one day meeting in September 2008 with relevant companies/industry members to discuss how the industry intends to increase the rate of compliance with this IRM plan requirement.

Against that backdrop of decreasing compliance, two companies have approached the CFIA with IRM plans with alternative refuge requirements. The CFIA does not dispute that IRM plans with different refuge requirements could be scientifically valid, but if they are not applied correctly, the validity of this science is lost. Part of the risk management process in Canada includes CFIA confidence that all conditions for the management of risk will be met by the proponent. The CFIA is concerned that authorizing the environmental release of Bt corn products with IRM plans with various refuge requirements, whether it be size or even layout, will create a complicating factor in growers' compliance with IRM requirements at large (i.e., that compliance will decrease even further), even more so if growers buy seed from 2 or 3 different companies. For example, a producer might plant a 5% refuge for a hybrid that requires a 20% refuge. Alternatively, if they buy seed

from 2-3 companies, they may opt to apply the simplest IRM plan of all three products across the board.

Currently, industry has not been able to maintain compliance with the current "generic" plans; therefore, there is concern that industry will not be able to ensure the proper application/implementation of IRM plans with varying refuge requirements (i.e., that an IRM plan will be correctly applied to the authorized product, and only to the authorized product). Prior to moving forward, CFIA regulators must not only have internal discussions, but also discussions with industry and other relevant stakeholders on how industry will ensure that the requirements for different IRM plans will be met on an ongoing basis. The CFIA plans to discuss this at the September 2008 meeting as well.

The purpose of Thursday's conference call is to discuss whether the EPA has similar concerns and internal discussions as the CFIA. Furthermore, the CFIA would like to involve the EPA in its discussions with industry at the September 2008 meeting.

I hope this helps to fill in the gaps a bit, and we look forward to talking to you tomorrow.

Kind regards,

Lucy

Tomya Fielding

Lucy Reed, M.Sc.

(613) 221-4704 | reedle@inspection.gc.ca | Facsimile / Télécopieur :

(613) 228-6140

Plant Biosafety Management Specialist, Canadian Food Inspection Agency

Spécialiste, gestion de la biosécurité végétale, Agence canadienne d'inspection des aliments

59 Camelot Drive | 59, promenade Camelot Ottawa ON K1A 0Y9 Government of Canada | Gouvernment du Canada www.inspection.gc.ca

Jew complimee inspection every 2 yrs

of Grover's field by CFIB Volunters

of Grover & field by CFIB Volunters

of Grover & field by CFIB Volunters

of Grover & fill by CFIB Volunters

of Grover & Complying to See of Complying w/

to make part of proposition and the make part of complime to the formal to the formal of complime to the formal that the complime to the grown of the g



To Mike Mendelsohn/DC/USEPA/US@EPA

CC

bcc

Subject Fw: A PS to our last meeting...- Please comment and CC me

Mike-

My understanding is that we want the following from Zig/ Annabel Eco team:

Annabel has an understanding of what we need which includes:

- (1) A memo or DER for the "Peer reviewed published literature summarizing one hundred field tests over 10 years" that we can use for these registrations and others that are pending or come in the future.
- (2) Clarification in writing preferably about the need for additional non-target insect testing on actual foilage from the two new registrations MON 89034 and MON89034 x 88017. Onlyone insect was tested with foilage with the Bt proteins incorporated.
- (3) A memo or DER that expresses in writing why we are accepting the synergy information, and that explains in more detail what published literature we are relying upon.
- (4) The eco-chapter that had been prepared earlier with clarifications mentioned above about cited literature, any additional confirmatory data needed and a signature page.

Mike- This is just from my memory, I am sure I missed something, please comment.

Thanks for all your help on this!!!

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

----Forwarded by Susanne Cerrelli/DC/USEPA/US on 04/14/2008 11:23AM ----

To: Susanne Cerrelli/DC/USEPA/US@EPA From: Zigfridas Valtuzis/DC/USEPA/US

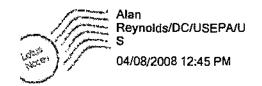
Date: 04/12/2008 12:16AM

cc: Alan Reynolds/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Annabel

Waggoner/DC/USEPA/US@EPA
Subject: A PS to our last meeting...

Susanne:

I apologize for my unfriendly attitude at the meeting on the $MON89034 \times MON88017$ PIP the other day. I was overwhelmed with shock after all the work that we put into that BRAD chapter. And it was one of the best ones that we had come up with until Annabel did the VipCot. I could not help but overreact when all I perceived at the meeting was uninformed picky criticism. I guess that I have not yet gotten used to that even after all these



To Susanne Cerrelli/DC/USEPA/US@EPA

CC

bcc

Subject Re: Fw: Edits and Additions to MON 89034 and MON 89034 x MON 880 t7 - What about sweet corn IRM??

Hi Susanne-

The sweet corn part is OK.....Monsanto's response was acceptable and they don't need to provide any more data.

The terms and conditions for sweet corn should mimic those for other Bt sweet corn registrations (i.e. Syngenta's Attribute sweet corn). I think we have some language regarding crop destruction in lieu of a refuge. Mike should be able to help find the language....if not, I can help you tomorrow.

Alan

Susanné Cerrelli/DC/USEPA/US



Susanne Cerrelli/DC/USEPA/US 04/08/2008 10:24 AM

To Alan Reynolds/DC/USEPA/US@EPA

CC

Subject Fw: Edits and Additions to MON 89034 and MON 89034 x MON 88017 - What about sweet corn IRM??

Alan-

I am getting pressure from Monsanto and mike to wrap up the PA letter. Please let me mike was asking me about sweet corn, and your know if you have comments today. review

of MON 89034 states: BPPD agrees that no structured refuge is needed in conjunction with the sweet corn use based on the destruction of potential resistant larvae through cultivation practices.

Can you confirm that we don't need anything more for sweet corn? Sharlene had asked for data and expression and activity last year for sweet corn. Was monsanto's response totally ok for sweet corn IRM??

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

---- Forwarded by Susanne Cerrelli/DC/USEPA/US on 04/08/2008 09:56 AM ----





Annabel Waggoner/DC/USEPA/US 02/17/2008 06:00 PM

To Zigfridas Vaituzis/DC/USEPA/US@EPA

CC

bcc

Subject Additive vs. Synergistic effects

History:

This message has been replied to and forwarded.

Hi Zig,

Here's is some info' of **Additive vs. Synergistic** effects that I pulled from Alan Raybould's paper. I also attached the paper for you as well. Hopefully, it's the right one...

"The most powerful test of the hypothesis that the hazard is not greater than additive (not synergistic) is to examine the effects of the mixture in species that are sensitive to at least one of the proteins; If a species sensitive to both proteins is available, dose response curves for the separate proteins would be obtained. The predicted response of the species to mixtures of the proteins can be obtained from these data.

The predicted effect depends upon the modes of action of the proteins. If the proteins have different modes of action, the predicted effect of the mixture should be calculated using a model called independent joint action. Under this model, if a certain amount of protein A alone kills x% of a sample, and a certain amount of protein B kills y%, the predicted percentage kill of a mixture of these amounts of protein is given by x + y - (xy/t00) Colby (1967) If protein A kills x%, protein B will kill y% of the remainder, i.e. x + y/100(t00-x) = x + y - xy/100. The observed and expected mortalities are compared over a range of concentrations. There is no test of statistical significance; the predicted dose response curves are compared with the expected dose response curves and if there is greater mortality than expected over the range of concentrations the hypothesis of synergism is falsified. If the studies corroborate the hypothesis of no synergism in sensitive pest species, it is likely that there will be no synergism of the mixture against non-target organisms, and that the risk hypothesis of HQ <1 for all non-target organisms exposed to the mixture is corroborated. No testing of the mixture against non-target organisms should be necessary under these circumstances."



Raybould.Eco.GM. crops.lisk.assessment.2007.pdf

Annabel Waggoner, Environmental Protection Specialist U.S. Environmental Protection Agency Office of Pesticide Programs Biopesticides and Pollution Prevention Division Microbial Pesticide Branch (703) 308-0340 waggoner.annabel@epamail.epa.gov

Mailing Address:
OPP/ Biopesticides and Pollution Prevention Division Mailcode: 75 t tP
U.S. EPA
t200 Pennsylvanía Avenue NW
Washington DC 20460

Brifing for MON 89034 +X Ble the conditions of regist of leptacher Brain ISSUES Soul Faile

Non target used (B) Smart Strek-O Synengism Bordong deuserons (i) Zig & add Signihore block ov mano (2) Do If pernst In right of data come aportoct of that previously nota andyris supercedes Zegs reviews

(44)

on part 5) outlingate receives done Two have forgrendly required for duta over the past -- 10 yrs "
The forger -- (describe fulnes) Just 3 snottstel The Kener agrees to the conclusions of this paper [Issue 3] Soil degrandation of 10 ye sholy am Support soul degrathe 7 Could add chatron explantion 3 Sentence fund States EPA agrees possoon the paper Storley papers Support Andrelo General Summany newhorld in HAS 10gr.
publication "Consumos doc." July 7007 Jone 4 pag 7 - Swagetts citing the Support Schon 3 regulation Smed.

45)

Joseph Janes of Joseph Anthrong?

Vipcot sinengy an

Supertack >

Do we won! more data?

don't need more non-longer wifels

for this MON 89034 * X

(46)



To Zigfridas Vaituzis/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA, Annabel Waggoner/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA, Sheryl

bcc

Subject MON 89034 Eco Review

Zig,

My understanding of the the information we need follows. I will be out tomorrow but should be in the office for our briefing of Janet on Thursday.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
http://www.epa.gov/pesticides/biopesticides

Background

MON 89034 contains Cry1A, 105 and Cry2Ab2 MON 88017 contains Cry3Bb1

MON 89034 nontarget terrestrial invertebrate studies are limited to either Cry1A.105 or Cry2Ab2 studies except for Collembola where leaf tissue containing both proteins was tested.

Cry1A.105 is a chimeric protein created by Monsanto with domains from three Cry proteins, Cry1Ab, Cry1Ac, and Cry1F.

For the pending MON 89034 and MON 89034 x MON 88017 registrations, we have received the following nontarget organism assessments: (1) 12/14/2007 MON 89034 review of non-target invertebrate studies on Cry1A.105 and Cry2Ab2, (2) 12/14/2007 MON 89034 review of broiler, quail, soil fate, and endangered species, (3) 12/14/2007 MON 89034 x MON 88017 review regarding potential interactions between Cry1A.105, Cry2Ab2, and Cry3Bb1, and (4) a MON 89034 and MON 89034 x MON 88017 Environmental Assessment BRAD chapter that is unsigned and undated.

Since 2001, we have been requiring long term field studies for PIP soil degredation and non-target invertebrate impacts. Much of this data has been received and is awaiting final review. This data needs to be reviewed prior to November 2008 when we extend the registrations of ECB active Bt corn. Of these, the Cry1Ab long term soil fate data has been reviewed and we determined no further testing is necessary for Cry1Ab. I believe Cry1Ac soil fate has also been reviewed.

Several of us in MPB, including yourself, have exchanged emails and subsequently met on April 1st regarding regarding stacked/pyramid PlPs and additive vs. synergistic effects. In a 3/28 email you mentioned that "[w]e are going to get more and more of them involving more

than 3 proteins, so the simple synergy/additive effect testing may no longer give us the information we want." During the April 1st meeting you further indicated that in some cases bridging data using target insect species may not be adequate and we may need to test representative nontarget organisms with the protein combinations.

Requests

- 1) Provide a signed version of the environmental assessment. In the past, this has been done by the eco team by providing a signature block and date at the beginning of the BRAD chapter.
- 2) Provide more explanation in the BRAD/ environmental assessment as to why the long term non-target invertebrate impacts studies are not being required. Specifically, provide more of a description of the Marvier et. al., and Sanvido et. al. studies cited.

Currently the BRAD chapter states:

The Agency expects that Tier 1 testing for short-term hazard assessment will be sufficient for most studies submitted in support of PIP registrations. However, if long range adverse effects must be ascertained, then higher-tier longer-term field testing will be required. As noted above, the October 2000 SAP and the National Academy of Sciences I (NAS 2000) recommended testing non-target organisms directly in the field. This approach, with an emphasis on testing invertebrates found in corn fields, was also recommended by the August 2002 SAP and was supported by several public comments. Recent analyses of short term and long term field study effects on invertebrate populations in Bt corn and cotton fields indicate that no unreasonable adverse effects are taking place as a result of wide scale Bt crop cultivation. Slight reductions in some invertebrate predator populations are an inevitable result of all pest management practices which result in reductions in the abundance of the pests as prey. Based on these considerations, regulatory testing of the specialist predators and parasitoids of target pests may eventually be considered unnecessary.

t (Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation is available from the National Academy Press, 2101 Constitution Avenue, N.W., Lockbox 285, Washington, DC 20055; (800) 624-6242 or (202) 334-3313 (in the Washington metropolitan area); https://www.nap.edu. 2Marvier, M., McCreedy, C., Regetz, J. & Kareiva, P. A meta-analysis of effects of Bt cotton and maize on nontarget invertebrates. Science 316, 1475-1477 (2007). Sanvido,O., Romeis, J., Bigter, F. (2007). Ecological Impacts of Genetically Modified Crops: Ten Years of Field Research and Commercial Cultivation. Adv Biochem Engin/Biotechnol 107: 235-278

3) Provide more explanation in the BRAD/ environmental assessment as to why the long term soil degradation studies are not being required. The Cry1Ab study reviewed by Tessa and cited in the BRAD chapter has been reviewed. However, Cry1F, Cry3Bb1 x Cry1Ab, and several other long term soil degradation studies are pending final review. Please further explain the underlying basis for "no detectable Cry protein accumulation in agricultural soils."

Currently the BRAD chapter states:

...More specifically, a study that evaluated Cryl Ab protein accumulation in a field with three years of continuous Cryl Ab field corn production showed that the protein had not accumulated in soil to a level that would elicit a toxic response from ECB larvae, a species that is highly susceptible to Cryl Ab protein (Milofsky, 2006).

No additional soil degradation studies are required for Cry2Ab2 or Cry1A.105 proteins. As a result of FIFRA Scientific Advisory Panel recommendations and public comments, the Agency has been receiving three year soil fate studies for the currently registered Cry protein producing crops grown in a variety of soils and environmental conditions. The results show that there is no detectable Cry protein accumulation in agricultural soils during commercial planting of currently registered Cry protein producing crops.

- 4) Update p. 7 of the BRAD chapter regarding protein interaction in accord with the 12/14/2007 review. The cited 7/6/06 Hunter review states "The study report is classified as supplemental. The study is upgradeable to "acceptable" when test replication and insect numbers are reported. In addition, this study is classified as unacceptable for Section 3 registration."
- 5) Confirm that the 12/14/2007 potential interaction review agrees with your current position of potential protein interactions in light of discussions and emails in MPB regarding stacked/pyramid PIPs and additive vs. synergistic effects. Specifically, confirm that no additional non-target data on the stacks of the proteins are necessary.

Zigfridas Vaituzis/DC/USEPA/US



Zigfridas Vaituzis/DC/USEP A/US 04/12/2008 12:16

To Susanne Cerrelli/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Annabel Waggoner/DC/USEPA/US@EPA

Subject A PS to our last meeting...

Susanne:

I apologize for my unfriendly attitude at the meeting on the MON89034 x MON88017 PIP the other day. I was overwhelmed with shock after all the work that we put into that BRAD chapter. And it was one of the best ones that we had come up with until Annabel did the VipCot. I could not help but overreact when all I perceived at the meeting was uninformed picky criticism. I guess that I have not yet gotten used to that even after all these years.. [and I keep on telling Annabel to get used to it already!]. It is my goal to get used to it before I retire. If I keep on reacting as I did the other day, I will have to hang around for too many more years in order to learn... or leave as a failure...)-:

Unfortunately, my response did not give opportunity for you to express all that you need. What is it you need?

From some of the comments I heard I surmise you would like a Memo summarizing the Ecorisk assessment. But the introduction summary and the conclusion at the end of the document have the information that would go into a Memo. A memo was not prepared because the memos were written when all that the RALs received was the DERs and a Memo. With that the RALs had to write the BRAD chapter. Because now the science staff is preparing the chapter for the BRAD, a summary Memo is unnecessary. Or is it? Could be that you need one for the Fact Sheet? - let me know what it is you want. But I still maintain that the BRAD chapter has all of the necessary information and all one has to do is block and paste from the summary and conclusion sections... into a fact sheet.

As for the Memo that Mike wants saying that we no longer require long term soil studies and field testing - that was said in the BRAD for this product with the published literature as justification. Peer reviewed published literature summarizing one hundred field tests over 10 years of use carries much more credibility that one of two studies by a registrant. And not

asking for these studies needs to remain as a 'waiver' on a case-by-case basis. We can waive it for the well-known Bt proteins that have been on the market for years. The data may become again necessary for the next product that comes in the door. A signed 'policy' memo waiving the requirement would pick up a life of its own and would be used by registrants to argue that we ceased that requirement for good. It is not our intent to cease field and soil testing for all future PIPs. [A written policy memo would have to clearly define where we draw the line - and who knows where to draw the line when we have no idea what the industry is coming up with next?]

So now that I am over the 'shock' - let me know if you still need something from us, within reason... In general I recommend that if there are issues that are not clear to you- as long as the registration is not being held up - take the word of the science team and get on with it.. that is why we are the scientists. The RALs are not expected to do or critique science [except where the scientists ignore the OPP SOPs and FIFRA requirements].

Don't let my poor attitude keep you from asking for the information that you need to get your job done. My poor attitude is my problem, not yours.

Peace!

[zig.v]

Zig Vaituzis, Ph.D., Team Leader Environmental Risk Assessment Team Biopesticides and Pollution Prevention Division USEPA (7511P) 1200 Pennsylvania Ave., N.W. Washington, D.C. 20460.000 t

Tel: 703-308-8676 Fx: 703-308-7026

vaituzis.zigfridas@epa.gov



Mike Mendelsohn/DC/USEPA 04/04/2008 t2:48 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

CC

bcc

Subject Edits and Additions to MON 89034 and MON 89034 x MON 880 t7

PA Letter

History:

This message has been forwarded.

Susanne,

Thanks for sending the initial draft. I made some edits and additions. I combined the 2 PA letters into one, used the PA letter format, and tried to use track changes. We need to check with Alan re: sweet com requirements and monitoring for fall armyworm. The edited letter is attached FYI. I have also provided a link to the 2001 reassessment. You can find sweet com requirements there under the IRM section, http://www.epa.gov/oppbppd1/biopesticides/pips/bt_brad.htm.

Mike Mendelsohn Senior Regulatory Specialist Office of Pesticide Programs/ Biopesticides and Pollution Prevention Division (7511P) U.S. Environmental Protection Agency

1200 Pennsylvania Avenue NW Washington DC 20460

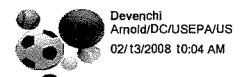
(703) 308-87 t5

(703) 308-7026 (fax)

http://www.epa.gov/pesticides/biopesticides



4 PA 4 3 2008.doc



To Susanne Cerrelii/DC/USEPA/US@EPA

CC

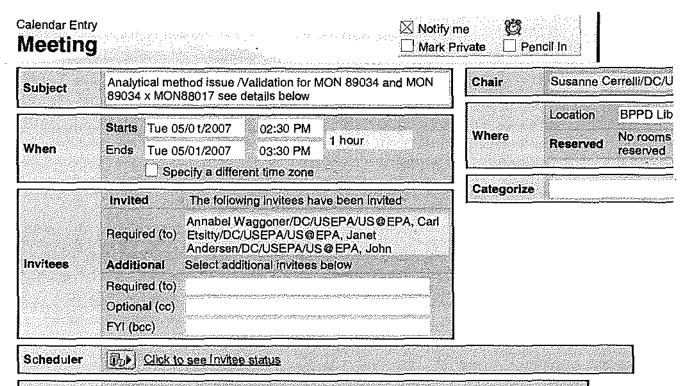
bcc

Subject FOIA Request RIN-0616-08

Hey Susanne, the DERs that I need are for MRID numbers 469513-04, -05, -06, 469514-13, -14 and -30. I have check Reg.gov and noticed that the studies are listed on there so releasing these DERs will not be a problem. Thanks a lot for any help you can provide with getting these. If there are any questions please feel free to contact me.

DeVenchi P. Arnold Information Management Specialist OPP/ITRMD/PIRIB (7502-P) U.S. Environmental Protection Agency Washington, D.C. 20460 (703)305-5698 Fax: 703-305-5480

Visit OPP's new FOIA Website: http://www.epa.gov/pesticides/foia/



Description

Rebecca- requested feedback on Monsanto's request below. If there are other items to add please email Susanne. THANKS!!!

Dear Ms. Cerrelli,

I would appreciate clarification on the first request:

1. Validated detection method protocols and independent lab

validations of the detection methods for CrylA.105 and Cry2Ab2 in

corn need to be submitted.

Monsanto submitted confirmation of a protein-based method that detects

Cry2Ab2 in corn and will allow to separate MON 89034 from all corn

currently on the market to EPA (MRID 46694503) in November 2005. This

method was not yet validated by the third party. This validation will

take place at the end of 2007 when most advanced hybrids will be

available. Previously, such detection method was provided to the Agency

46951303

(MSL0020479), 46951403 (Study 05-01-39-32, MSL 20285).

4. Discuss determination of equivalence between microbially-produced and plant-produced CrylA.105 using the bioactivity assay (described in MRID 46694604). Were

statistics used? Why was the acceptance criteria determined to be <4

fold

difference between the mean EC50 values in the corn earworm diet-incorporation insect bioassay?

5. Explain the discrepancy in the EC50 definitions given on pages 11 and 8 in MRID 46951405.

Also, we request electronic copies of the following studies: MRIDs 46951403 (Study 05-01-39-32, MSL 20285)?need tables only, 46951404 (MSL-20071)?need figures only, 46951405 (MSL-20132; Study 05-01-39-23),

46951407 (MSL-19931; Study 05-01-62-04)?need figures only, 46951303 (MSL0020479)?need tables only, 46951408 (MSL-19930; Study 05-01-62-03)?need figures only, 46951409 (MSL-19938; Study 05-01-62-05)?need figures only, 46951402 (MSL-20311, Study

05-01-39-12)?need figures only.

Your efforts to address these in a timely manner, would be greatly appreciated. Of course if this is not possible, the PRIA date may need

to be renegotiated. Please note that additional deficiencies may be noted in the future as the evaluations are not completed at this time.

If you have any questions concerning this request, please contact Susanne Cerrelli at 703-308-8077.

Regards,

1

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077 (w)

Rebecca Edelstein/DC/USEPA/U S

12/22/2006 09: t0 AM

To Sharlene Matten/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

cc Mike Mendelsohn/DC/USEPA/US@EPA

bcc

Subject Re: letter to monsanto- OK?? MON89034x Mon88017 and MON 89034 Th

I will probably need some SOPs from Monsanto, but it'll take me awhile to figure out exactly what I need, so don't wait on me-- go ahead and send the letter. I just have one comment on the letter— we have expression level data for the stacked product and the individual events (separate studies), so I'm not sure what we're asking for in item 1.

Rebecca Sharlene Matten/DC/USEPA/US

> Sharlene Matten/DC/USEPA/US 12/21/2006 05:38 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

Mike Mendelsohn/DC/USEPA/US@EPA, Rebecca

Edelstein/DC/USEPA/US@EPA

Re: letter to monsanto- OK?? MON89034x Mon88017 and

Subject MON 89034

Susanne — I concur with this letter. Thank you for letting me see it before it goes forward. Sharlene

Susanne Cerrelli/DC/USEPA/US



Susanne Cerrelli/DC/USEPA/US

12/21/2006 04:04 PM

To Mike Mendelsohn/DC/USEPA/US@EPA

Sharlene Matten/DC/USEPA/US@EPA, Rebecca Edelstein/DC/USEPA/US@EPA

Subject letter to monsanto- OK?? MON89034x Mon88017 and MON 89034

Here's the letter again. Rebecca do you need anything else for your review? If you need much more time we can deal with your needs in a separate communication to Monsanto.

[attachment "524-LTA" and LTL screen4.doc" deleted by Rebecca Edelstein/DC/USEPA/US]

Mike-I also need to check with you about PRIA dates for this submission.

Thanks!!

⊕ ЕРА	Environmenta	ited States I Protection Agent pton, DC 20460	cy	Registration Amendment Other	OPP Identifier Number
	Applicatio	n for Pesticide – S	Section I		
t. Company/Product Number File S	ymbol 524-LTL	2. EPA Produc	n Manager Sheryl Reilly	3. Propos	ed Classification
Company/Product (Name) MG	ON 89034	PM#	90	⊠ Nor	ne Restricte
5. Name and Address of Applicate Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167		my product is s EPA Reg. No	i Review. In accordant in control	omposition and labeli	ng to:
		Section - II			
Notification – Exp Explanation: Use additional p. Application to Regis	response to Agency letter dated	on I and Section II.) ted Protectant Bacille		n. w. Cryl A.105 and	
		Section – III			
1. Malerial This Product Will B Child-Resistant Packaging Yes* No Certification must be submitted	Unit Packaging Yes No If "Yes" No.	Water Soluble P Yes No Per If "Yes" tainer Package wgt.	No. per Container	Type of Container Metal Plastic Glass Paper Other	
Label Contents Inform	aation 4. S	ize(s) Retall Container	5. Locat	ion of Labet Direction Label Labeling accompany	
i. Manner in Which Label Is Affixe	d to Product	Lithograph	Other	Laveling accompany	und broduct

Paper glued Stenciled Section - IV t. Contact Point (Complete items directly below for Identification of Individual to be contacted, if necessary, to process this application.) Name Telephone No. (Include Area Russell P. Schneider Sr. Director, Regulatory Affairs & Code) (202) 383-2866 Policy Certification 6. Date Application I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. Received I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. (Stamped) 3. Title Signature Regulatory Affairs Manager 5. Date 4. Typed Name Yong Gao, Ph.D. Tel. (314) 694-2943 May 22, 2008

Please read instructions on reverse before completing form. EPA Form 8570-1 (Rev. 3-94) Previous aditions are obsolete.

Form Approved. OMB No. 2070-0060. Approval Expires 2-28-95
Whits - EPA File Copy (original) Yellow - Applicant Copy



Restricted

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for the registration and 0.25 hours per response for reregistration and special necessary forms. Send comments regarding burden estimate or any court burden to Director, OPPE Information Management Division (2137), U. Do not send the completed form to this address.	review activities, including time other aspect of this collection of	for reading the instructions and completing the information, including suggestions for reducing the
Certification with	Respect to Citation of	f Data
Applicant's/Registrant's Name, Address, and Telephone Number:	· · ·	EPA Registration Number / File Symbol:
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 6	3167 (314)-694-2943	S24-LTL
Active Ingredient(s) and/or representative test compound(s): Bacillus (Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) nece MON 89034.		Date: May 22, 2008
General Use Pattem(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name:
Terrestrial field crop		MON 89034
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submil the Formulator's Exemption		
I am responding to a Data-Call-in Notice, and have included v should be used for this purpose).	rith this form a list of companies	s sent offers of compensation (the Data Matrix form
Section I: METHOD OF DA	TA SUPPORT (Check of	one method only)
I am using the cite-all method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective me	selective method of support (or cite-all option under ethod), and have included with this form a of data requirements (the Dala Matrix form must be
Section II: GE	NERAL OFFER TO PA	NY
[Required if using the cite-all method or when using the cite-a	***************************************	
I hereby offer and agree to pay compensation, to other person	ns, with regard to the approval o	f this application, to the extent required by FIFRA.
	I: CERTIFICATION	
I certify that this application for registration, this form for reregistration for registration, the form for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie under the data requirements in effect on the date of approval of this apsimilar composition and uses.	II-in response. In addition, if the ia in the Agency's files that (1) on this in this product; and (2) is a	e cite-all option or cite-all option under the selective concern the properties or effects of this product or type of data that would be required to be submitted
I certify that for each exclusive use study cited in support of this oblained the written permission of the original data submitter to cite that	s registration or reregistration, t t study.	hat I am the original data submitter or that I have
I certify that for each sludy cited in support of this registration of submitter; (b) I have obtained the permission of the original data subscompensation have expired for the study; (d) the study is in the public have offered (i) to pay compensation to the extent required by section determine the amount and terms of compensation, if any, to be paid for	mitter to use the study in suppi c literature; (e) I have notified li ions 3(c)(1)(F) and/or 3(c)(2)(E	ort of this application; (c) all periods of eligibility for a mixing the company that submitted the study and
I certify that In all instances where an offer of compensation is a accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are avail such evidence to the Agency upon request, I understand that the Agency conformity with FIFRA.	lable and will be submitted to the cy may initiate action to deny, c	ne Agancy upon request. Should I fail to produce ancel or suspend the registration of my product in
t certify that the statements t have made on this form and al knowingly false of misleading statement may be punishable by fin	l attachments to it are true, ac e or imprisonment of both un	ccurate, and complete. I acknowledge that any der the applicable /aw.
Signature	Date	Typed or Printed Name and Title
18 cres	May 22, 2008	Yong Gao, Ph.D. Regulatory Affairs Manager

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX				
Date: May 22, 2008				EPA Reg. No	o./File Symbol: 524-LT	L Page 1 of 12
Applicant's/Registrant's Name 8					<u>.</u>	
	00 N. Lindbergh Blvd., St. Louis, MO 631				MON 89034	
Ingredient Bacillus thuring Identifier: MON-89034-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary	for their Produ	action in MON 89034 (6	DECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bocillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMtR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3).		Monsanto Com	pany	OWN	
885.1100	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cryl A. 105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	469514-01	Monsanto Com	pany	OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.R., Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Con	pany	OWN	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cryl A. 105 and Cry2 Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	469514-03	Monsanto Con	pany	own	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Le vine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Cont Grain of MON 89034 and Companison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	469514-04	Monsanto Con	ıpany	OWN	Product Characterization
Signature	e Gra		Name and Title Yong Gao, Ph.D. Regulatory Affairs M		Date May 22, 2008	440

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: May 22, 2008			E	PA Reg. No./File Symbol: 524-LTL	, Page 2 of 12
	00 N. Lindbergh Blvd., St. Louis, MO 6316			roduct: MON 89034	
Ingredient Bacillus thurings Identifier: MON-89Ø34-3)	iensis Cryl A.105 and Cry2 Ab2 Proteins and the Genetic	Malerial (Vector P	V-ZMIR245) Necessary for	Their Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.I t00	Levine, S.L. and J. Uffinan. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E.Coli and Bt Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	469514-05	Monsanto Compan	ıy OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Sunmary of Southern Blot Analysis of MDN 89034 and MON 89597 Corn. Monsanto Technical Report MSL-20068	466945-0 t	Monsanto Compan	ıy OWN	Product Characterization
885.1100	Goertz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cryt A.105 Protein Purified from the Com Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.co/i-Produced Cryt A.105 Proteins. Monsanto Teclinical Report MSL-19960.	466946-04	Monsanto Соппран	ıy OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Com MON 89034".	471275-03	Мопѕапто Сопраг	ny OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry I A. 105 and Cry2 Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	471275-05	Monsanto Compar		Product Characterization
Signature	ng God Parage parsions available Submit only Baser year		Name and Title Yong Gao, Ph.D. Regulatory Affairs Man		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX				
Date: May 22, 2008				EPA Reg. No	o./File Symbol: 524-LTL	Page 3 of 12
Applicant's/Registrant's Name &		·····	······································		······································	
Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 631	67		Product: N	MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	tensts Cry1A,105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary	for their Produ	action in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submitter		Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Fonctional Similarity of the Cryt A.105 Protein to Cryl A Class of Bucillus theringiensis Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsauto Com	pany	OWN	Product Characterization
860.1340	Dudín, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Com	pany	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2 Ab2 protein. Monsanto Study CRO-2005-049.	469514-06	Monsanto Com	pany	OWN	Human Health Assessment
885.1100	Kanadia, S.A. and E.A. Rice. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Mousanto Technical Report MSL-1993 t.	469514-07	Monsanto Com	pany	own	Human Health Assessi ne nt
885.t100	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cry t A. 105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Com	pany	own	Human Heattu Assessment
Signature	97) Flactronic and Paner versions available. Submit only		Name and Title Yong Gao, Pt.D. Regulatory Affairs M	anager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	n, DC 20460. Do not send the form to this address.	TA MATRIX			
Dale: May 22, 2008		IIA MAIRIA		EPA Reg. No./File Symbol: 524-LTI	, Page 4 of I2
Applicant's/Registrant's Name &	Address:				
	00 N. Lindbergh Blvd., St. Louis, MO 631			Product: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	iensis CryIA.105 and Cry2Ab2 Proteins and the Geneti	c Malerial (Vector P	V-ZMIR245) Necessary fo	or their Production in MON 89034 (C	DECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Stalus	Nole
885.1100	McCoy, R.L. and A. Silvanovich. 2005. Bioinformatics Analysis of the Cryl A. 105 Protein Utilizing the ADS, TOXINS, and ALL PEPTIDES Databases. Monsanlo Technical Report MSL-19686.	466946-05	Monsanto Compa	ny OWN	Human Healdt Assessment
885.1100	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Minisanto Technical Report MSL-19938	469514-09	Monsauto Compa	iπy OWN	Human Health Assessment
885.1100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	469514-10	Мопѕалю Солгра	iny OWN	Hwnan Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cryl A.105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	466946-06	Mousanto Compa	iny OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	466946-07	Монѕатю Сонгра	uiy OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Aeute Oral Toxicity Study in Mice with Cry1A.105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Соппра		Human Health Assessment
Signature 5	s and		Name and Title Yong Gao, Ph.D. Regulatory Affairs Man	Date May 22, 2008	



Monsanto Company

©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 in Ottect, O.TT., Washington	, DC 20460. Do not send the form to this address. DA	TA MATRIX				
Date: May 22, 2008				EPA Reg. No./Fite	Symbol: 524-LTL	Page 5 of 12
Applicant's/Registrant's Name & Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 6310				V 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	iensis Cryl A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary f	or their Production	in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Stalus	Note
885, t t00	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	469514-t1	Monsanto Com	pany	OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Controt or Commercial Corn. Monsanto Study 05-01-50-13, Amended Report.	469514-12	Monsanto Comp	рану	own	Human Health Assessment
N/A	MacRac, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry1A. 105 Protein. Monsanto Technical Report MSL- 20230.	469514-13	Monsauto Comp	oany .	оми	Environmentat Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.	469514-14	Monsanto Com	yany	own	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pesls in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	469514-15	Монзапто Сону	pány	OWN	Environmental Assessment
Signature 5	e Gu		Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma		nte ay 22, 2008	

EPA Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	n, DC 20460. Do not send the form to this address. DA	TA MATRIX			······································
Date: May 22, 2008			EPA	Reg. No./File Symbol: 524-LTL	Page 6 of 12
	00 N. Lindbergh Blvd., St. Louis, MO 631			tuct: MON 89034	
Ingredient Bacillus Ihuring Identilier: MON-89Ø34-3)	teusis Cry (A. 105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary for the	eir Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (Folsomia candida). Monsanto Technical Report MSL-20169.	469514-16	Monsanto Coliipany	OWN	Environmental Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran Daphnia magna: An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.	469514-17	Monsanto Company	OWN	Environmental Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cryt A.105 Protein in an Acute Study will the Earthworm in an Artificial Soil Substrate. Monsanto Teclinical Report MSL-20147.	469514-18	Monsanto Colnpany	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dictary Effect(s) of a Cryt A.105 Protein on Honeybec Larvae (Apis mellifero L.). Monsanto Study CA-2005-071.	469514-19	Monsanto Company	OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cty1A.105 Protein on Adult Honeybecs (Apis mellifera L.). Mousanto Study CA-2005-072	469514-20	Монѕалю Сонграну	own	Euvirounental Assessment
Signature	s Gra		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manage	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

06-CR-172E-3



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for Ihis collection of information is estimated to average 0.25 hours per response for registration and special review activities, including lime for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	n, DC 20460. Do not send the form to this address.	TA MATRIX				
Dale: May 22, 2008				EPA Reg. No.	/File Symbol: 524-LTL	Page 7 of 12
	00 N. Lindbergh Blvd., St. Louis, MO 631				1ON 89034	
Ingredien] Bacillus thuring Identifier: MON-89Ø34-3)	giensis CryIA.105 and Cry2Ab2 Proteins and the Genet	lic Maleriat (Vector	PV-ZMIR245) Necessary	for their Produ	uction in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Sludy Name	MRID Number	Submiller		Slatus	Nole
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, Coleomegilla maculara (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.	469514-21	Мопѕапю Сопіј	oany	own	Environmental Assessment
885,4340	Paradise, M.S. 2006. Evaluation of Potential Dictary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Coleomegilla maculota (Coleoptera; Coccinellidae). Monsanto Technical Report MSL-20151.	469514-22	Monsanto Comy	sany	own	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsanto Com	oany	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridac). Monsanto Technical Report MSL-20171.	469514-24	Monsanto Com	oany	own	Environmental Assessment
8 85 <u>.43</u> 40	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae). Monsanto Teclinical Report MSL-20149.	469514-25	Monsanto Colli	pany	OWN	Environmental Asse <u>ssme</u> nt
Signature	23 02		Name and Title Yong Gao, Ph.D. Regulalory Affairs Ma		Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submil only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Dale: May 22, 2008				EPA Reg. No./File Symbol: 524-LTI	Page 8 of 12
Applicant's/Registrant's Name &					
	00 N. Lindbergh Blvd., St. Louis, MO 631			Product: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	giensis Cryl A.105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector P	V-ZMIR245) Necessary for	or their Production in MON 89034 (DECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dictary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanto Compa	ny OWN	Environmental Assessment
885.5200	Muelli, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	469514-28	Monsanto Colinpa	ny OWN	Environmental Assessment
N/A	Huesing, J.E., J.J. Dnan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Compa	ny OWN	Environmental Assessment
N/A	MacRae, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bocillus Thuringiensis Proteins Cryl A. 105 and Cry2 Ab2. Monsanto Technicat Report MSL-19859.	466946-02	Monsanto Compa	iny OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasine Wasp, Ichneumon pramissorius (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	469514-26	Mousauto Compa		Environmental Assessment
Signature	A and		Name and Title Yong Gao, Ph.D. Regulatory Affairs Mar	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX				
Date: May 22, 2008				EPA Reg. No.	/File Symbol: 524-LTL	Page 9 of t2
Applicant's/Registrant's Name &						
	00 N. Lindbergh Blvd., St. Louis, MO 631			l	ION 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	giensis Cryl A, 105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector P	V-ZMIR245) Necessary	for their Produ	iction in MON 89034 (C	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Slatus	Note
885.4340	Palmer, S.J. and H.O. Krucger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthronn io an Artificial Soil Substrate. Monsanto Technical Report MSL-16177	45 <u>08</u> 63-13	Monsanto Com	рану	own	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified Bacillus thuringiensis Cry2Ab2 protein on lioney beclarvae. Monsanto Technical Report MSL-16961.	45337t-02	Monsanto Com	pany	OWN	Environmental Assessment
885.4340	Teixcira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (Folsomia candida), Amended report. Monsanto Technical Report MSL-16174.	450863- † 4	Monsanio Com	pany	OWN	Environmental Assessment
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (Nasonia vitripennis). Monsanto Technical Repon MSL-16173.	450863-t0_	Monsanto Con	pany	own	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technical Report MSL-16176.	450863-08	Mousanto Cor	ipany	ow <u>n</u>	Environmental Assessment
Signature 5			Name and Title Yong Gao, Ph.D. Regulatory Affairs M	anager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

	DA	TA MATRIX			
Dale: May 22, 2008			EPA (Reg. No./File Symbol: 524-LTL	Page 10 of 12
Applicant's/Registrant's Name &					
	00 N. Lindbergh Blvd., St. Louis, MO 631		Produ		
Ingredient Bacillus thuring Idcutifier: MON-89Ø34-3)	riensis Cry1A.105 and Cry2Ab2 Proteins and the Genet	ic Material (Vector I	V-ZMIR245) Necessary for the	eir Production in MON 89034 (O	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.	469514-30	Monsanto Company	OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of Bacillus thuringiensis Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins in Insect-Protected Corn MON 89034 and MON 89034 x MON 88017		Monsanto Company	own	B e nefîits
	Bogdanova, N., S. Dubelman, M. Mueth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect- Protected Corn MON 89034 (MRID 46951428)	471403-01	Monsauto Company	OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Com MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	471275-01	Monsanto Company	OWN	Misc.
	Bogdanova, N, (2007). Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Company	OWN	Misc.
Signature	+ Gne		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊗EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any olher aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency,

401 M Street, S.W., Washingtor	, DC 20460. Do not send the form to this address.						
	DA	TA MATRIX					
Date: May 22, 2008				EPA Reg. No./File Symbol: 524-LTL		Page 11 of 12	
Applicant's/Registrant's Name &							
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 89034			
Ingredient Bactffus /huring Identifier: MON-89Ø34-3)	glensis Cry1A, 105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector P	V-ZM1R245) Necessary 1	for their Prod	uction in MON 89034 (C	DECD Unique	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note	
152-31 152-34 152-35 885.3100	Not applicable since Cryl A. 105 and Cry2 Ab2 are plant incorporated protectants, are present at low levels, and there is little opportunity for deniral or ocular contact.						
152-32 885,3150	Not applicable since Cryl A.105 and Cry2Ab2 are plant incorporated protectants, are present at low levels, and there is little opportunity for human inhalation exposure. A pathogenicity determination is not applicable since Cry1.105 and Cry2Ab2 are not living organisms.						
152-33 885,3200	Not applicable since Cry1A, 105 and Cry2Ab2 proteins are neither infective nor pathogenic.						
152-36 152-37 152-38 885,3400	There is no clear published evidence that has demonstrated clinical allergic reactions to Bt crystal proteins. Monitoring for hypersensitivity incidents can be implemented after registration is gramed.						
152-39 885.3500	Not applicable since Cry1A.105 and Cry2Ab2 proteins are not living organisms.						
154-17 885.4100	A paultogenicity determination is not applicable since Cry1A.105 and Cry2Ab2 are not living organisms.						
154-18 885-4150	Not applicable since there is no reason to suspect that wild mammals would be any more sensitive to Cry1A.105 and Cry2Ab2 than laboratory mammals. Mammals do not possess Cry protein receptors. A pathogenicity determination is not applicable since Cry1A.105 and Cry2Ab2 are not tiving organisms.						
Signature			Name and Title Yong Gao, Ph.D. Regulatory Affairs Mar Agency Internal Use Co		Date May 22, 2008		



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX	,			
Date: May 22, 2008	EF	PA Reg. No./File Symbol: 524-LTL	Page 12 of 12			
Applicant's/Registrant's Name &	Address:				······································	
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167				Product: MON 89034		
	tiensis Cry1A.105 and Cry2Ab2 Proteins and the Genet		V-ZMIR245) Necessary for	their Production in MON 89034 (C	ECD Unique	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
154-2 t 885.4280 154-22 885.4300	Results of acute toxicity tests with Daphnia did not produce any evidence of adverse effects. Testing with estuarine and marine species is not warranted because of very low to no potential for exposure to the Cry1A. t05 and Cry2Ab2 proteins from field corn. A pathogenieity determination is not applicable since Cry1A. t05 and Cry2Ab2 are not living organisms. Cry1A.105 and Cry2Ab2 are insect toxins and Cry proteins have never been shown to cause toxicity in aquatic and terrestrial plants. The risk of outerossing to weedy wild relatives is virtually nonexistent.					
Signature Signature		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manag	Date May 22, 2008	1 1 1		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington,	•			
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated response for reregistration and special review activities, including time for reading the instructions and comple other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.	to average 0.25 hours pe	. Send comme	ents regarding the burde	en estimate or any
DATA MATRIX				
Date: May 22, 2008		EPA Reg. No	o./File Symbol: 524-LTL Page to:	
Applicant's/Registrant's Name & Address:	· · · · · · · · · · · · · · · · · · ·			
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus duringiensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector)	DV. 734ID745) Necessar	F	MON 89034	/OFCD Unique
Identifier: MON-89034-3)	r v-Ziviikz45) Necessai	y 101 (RCM F10)	auction in Mon 83034	(OECS Origin
Guideline Reference Number Guideline Study Name MRID Number	Submitte	Submitter		Note
	Monsanto Соп Monsanto Соп		OWN	Product Characterization
	Monsauto Company		OWN	Product Characterization
	Monsanto Con		OWN	Product Characterization
	Monsauto Cor		own	Product Characterization
Signature	Name and Title Yong Gao, Ph.D. Regulatory Affairs M		Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington, DC 204		DATA MATRIX			
		DATA MATICA			L Page 2 of 12
Date: May 22, 2008			EPA Re	EPA Reg. No./File Symbol: 524-LTL F	
Applicant's/Registrant's Name & Address			-	3.4031.0000.4	
Monsanto Company, 800 N. I				: MON 89034	
Ingredient Bacillus thuringiensis Ci Identifier: MON-89Ø34-3)	ry I A. 105 and Cry2Ab2 Proteins	and the Genetic Material (Vector PV	-ZMIR245) Necessary for their	Production in MON 89034 (OECD Unique
Guideline Reference Number Guide	line Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Monsanto Company	OWN	Product Characterization
			Moosauto Company	OWN	Product Characterization
			Monsanto Company	own	(²roduci Characterization
Signature	1 G	~>	Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

other aspect of this cotlection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Page 3 of 12 EPA Reg, No./File Symbol: 524-LTL Date: May 22, 2008 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3) Guideline Reference Number MRID Number Guideline Study Name Submitter Status Note Product OWN Characterization Monsanto Company Product Монялию Сошрапу ΩWN Characterization Human Health OWN Assessment Monsanto Company tiuman Health Monsanto Company OWN Assessment Human Heattu Monsalito Company OWN Assessment Signature Date Name and Title May 22, 2008 Yong Gao, Ph.D.

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Regulatory Affairs Manager



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: May 22, 2008 EPA Reg. No./File Symbol: 524-LTL Page 4 of 12

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034

Ingredient Bacillus thuringiensis Cryt A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier; MON-89034-3)

Guideline Referen	 MRID Number	Submitter	Stalus	Nole
		Monsanto Company	OWN	Human Health Assessment
		Mojisanto Company	OWN	Human Health Assessment
		Monsanto Company	OWN	Human Health Assessment
:		Monsanto Cumpany	OWN_	Human Health Assessment
		Monsanto Company	OWN	Human Health Assessment
		Monsanto Company	OWN	Human Itealth Assessment
Signature		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.



\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

		Washington, I	•			
response for reregistration and s other aspect of this collection of	ce: The public reporting burden for this collection of info special review activities, including time for reading the ir information, including suggestions for reducing the burd , DC 20460. Do not send the form to this address.	ormation is estimated to	o average 0.25 hours per fing the necessary forms.	. Send comme	ents regarding the burde	n estimate or any
	D	ATA MATRIX				
Date: May 22, 2008				EPA Reg. No	o./File Symbol: 524-LT	L Page Sof 12
Applicant's/RegisIrant's Name &						
	00 N. Lindbergh Blvd., St. Louis, MO 63		11 (2) (17) (12) 11	j	10N 89034	/ODOD *1
Ingredient Bacillus thuring Identifier: MON-89034-3)	giensis CryIA.105 and Cry2Ab2 Proteins and the Gen	etic Material (Vector P	V-ZMIR245) Necessary	tor their Proc	fluction in MON 89034	(OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
			Monsanio Com	pany	own	Human Health Assessment
			Monsanio Com	рапу	OWN	Human tlealth Assessment
			Monsunto Con	pany	own	Environmental Assessment
			Monsanio Com	ipany	own	Enviroumental Assessment
			Monsanto Con)pany	OWN	Environmental Assessment
Signature	250		Name and Title Yong Gao, Ph.D. Regulatory Affairs M		Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

06-CR-172E-3



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

	DATA MATRIX			<u></u>	
Date: May 22, 2008			EPA Reg. No	./Fite Symbol: 524-LTI	Page 6 of l2
Applicant's/Registrant's Name & Address:	I N. (0. (0. (0.			ON 00024	
Monsanto Company, 800 N. Lindbergh Blvd., St. Ingredient Bacillus thuringiensis Cryl A.105 and Cry2Ab2 Pro Identifier: MON-89Ø34-3)		V-ZMIR245) Nccessary		ON 89034 uction in MON 89034 (OECD Unique
Guideline Reference Number Guideline Study Name	MRID Number	Submitter		Status	Note
		Mousanto Coшр	any	OWN	Environmental Assessment
		Monsanto Comp	pany	OWN	Environmenta Assessment
		Monsanto Comp	oany	OWN	Environmenta Assessment
		Monsanto Comp	pany	OWN	Environmenta Assessment
		Monsanto Co <u>in</u>	pany	OWN	Environmenta Assessment
Signature 2 3 C	− ∪	Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma	inager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act NotIce: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

		DATA MATRIX	····		
Date: May 22, 2008			EPA Reg. I	No./File Symbol: 524-LTL	Page 7 of t2
Applicant's/Registrant's Name	& Address: 800 N. Lindbergh Blvd., St. Loui	s MO 62167	Bandanat	MON 89034	· I. ———————————————————————————————————
	giensis CrylA.105 and Cry2Ab2 Proteins a				CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Compану	OWN	Environmental Assessment
		e de la companya de	Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Enviroumental Assessment
			Monsanto Company	OWN	Environmentat Assessment
			Monsanio Company	OWN	Environ mentat Assessment
Signature	> C	0	Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address,

401 in Officer, G. 191, Trashington	, DC 20460. Do not send the form to this ac	DATA MATRIX			
······································		PAIA MAINIA			
Date: May 22, 2008			EPA Reg	ı. No./File Symbol: 524-LTI	Page 8 of 12
Applicant's/Registrant's Name &		1.00 (01.67		3.503 Y 0000 A	
	00 N. Lindbergh Blvd., St. Louis			MON 89034	OFCD II
ngredient <i>Bacillus tluring</i> Identifier: MON-89034-3)	giensis Cryl A.105 and Cry2 Ab2 Proteins a	and the Genetic Material (vector PV-	ZMIRZ45) Necessary for their I	Production III MON 89034 (OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number_	Submitter	Status	Note
					1
					Епліториечтя
			Mousanto Corupany	OWN	Assessinent
			Monsanto Company	OWN	Environmenta Assessment
			Asonsaite Company		
				ļ	
			Mousanto Company	OWN	En vironmenta Assessment
					1
					Environmenta
		: 	Monsamo Company	OWN	Assessment
				01101	Environment
Piomotrum			Monsauto Company	OWN Date	Assessment
Signature	<i></i>	Arrangement	Name and Title	May 22, 2008	
	John Cons		Yong Gao, Ph.D.	, 1000	
		!	Regulatory Affairs Manager	1	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX Date: May 22, 2008 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Ingredient Bacillus thuringiensis Cryl A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89034-3)

Guideline Reference Number	Guideline Sludy Name	MRIO Number	Submitter	Status	Note
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
			Monsanto Conmany	own	Environmental Assessment
			Mousanto Company	own	Environmental Assessment
			Monsanto Company	OWN	Environmental Assessment
Signature	2 - a		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

TO THE OLIVER OF THE PARTY OF T	iton, DC 20460. Do not send the form to this addr	DATA MATRIX		·	
		DATA MAINIA			<u> </u>
Date: May 22, 2008			EPA Reg.	No./File Symbol: 524-LTL	Page 10 of t2
Applicant's/Registrant's Nam				······································	
Monsanto Company,	800 N. Lindbergh Blvd., St. Louis,	MO 63167		MON 89034	
ngredient Bacillus thu dentificr: MON-89Ø34-3)	ringiensis Cryl A.105 and Cry2 Ab2 Proteins and	I the Genetic Material (Vector PV-	ZMIR245) Necessary for their Pr	oduction in MON 89034 (OE	CD Unique
Suideline Reference Numbe	r Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	<u>IRM</u>
			Monsanto Company	OWN	Benefits
			Monsanto Company	OWN	Misc.
		-	Monsanto Сопрапу	own	Misc.
			Monsanto Company	OWN	Misc.
Signature	2 2 6 0		Name and Title Youg Gao, Ph.D. Regulatory Affairs Manager	Date May 22, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

		DATA MATRIX			
ate: May 22, 2008			EPA Reg.	No./File Symbol: 524-LTL	Page 11 of 12
pplicant's/Registrant's Name &	Address:				
	00 N. Lindbergh Blvd., St. Louis,	MO 63167	Product:	MON 89034	
	riensis Cry I A. 105 and Cry2 Ab2 Proteins an		AIR245) Necessary for their P	roduction in MON 89034 (OECD Unique
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Signature	2 d Ce	Y	ame and Title ong Gao, Ph.D. egulatory Affairs Manager	Date May 22, 2008	



Monsanto Company

⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

		DATA MATRIX			
Date: May 22, 2008			E	PA Reg. No./File Symbol: 524-LTI	Page 12 of 12
Applicant's/Registrant's Name & / Monsanto Company, 800	Address: O N. Lindbergh Blvd., St. Louis, MO	63167	Pi	roduct: MON 89034	
ngredient <i>Bacillus thuringi</i> Identifier: MON-89Ø34-3)	ensis Cry1 A.105 and Cry2 Ab2 Proteins and the C	Present Control of the Present	V-ZMIR245) Necessary for	r their Production in MON 89034 (0	DECD Unique
Guideline Reference Number	Guideline Study Name	MRtD Number	Submitter	Status	Note
Signature \bigcirc	-d - Ca		Name and Title Yong Gao, Ph.D. Regulatory Affairs Mana	Date May 22, 2008	<u> </u>

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



Monsanto Company
1300 | (Eye) Street, NW
Suite 450 East
Washington, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
http://www.monsanto.com

May 7, 2008

Dr. Sheryl Reilly, Chief Microbial Pesticides Branch Biopesticides and Pollution Prevention Division (751 IP) United States Environmental Protection Agency Washington, DC 20460

Subject: Pre-Acceptance Letter for MON 89034 and MON 89034 x MON 88017

EPA Petition Numbers: 6F7142 and 6F7143 EPA File Symbols: 524-LTA, 524-LTL Application Date: September 29, 2006

Dear. Dr. Reilly:

This is a response of Monsanto Company to the above stated pre-acceptance letter dated May 6, 2008 from EPA with respect to Section 3 registrations of Monsanto's Bt corn MON 89034 (Cry1A.105 and Cry2Ab2) and MON 89034 x MON 88017 (Cry1A.105, Cry2Ab2, Cry3Bb1) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Monsanto Company accepts all the proposed conditions for registration with the following modification:

- 1) Page 2: the table, row 3, column 2, Monsanto will conduct a 7 to 14 day
 Daphnia study as per the 885 Series OPPTS Guidelines. The reason for
 changing 21 day to 7-14 day study is that the 21 day guideline was designed
 for testing microbial pesticides. For Bt proteins, the pathogenicity and
 infectivity is not an issue. The 2000 EPA-SAP and 2007 EPA white paper (ed,
 Robyn Rose) recommended to conduct a minimum 5 day, preferably 7-14
 days daphnia study for Bt proteins.
- Page 4: section a, 4th paragraph, last line, change "Monsanto PIP products" to "Monsanto corn PIP products." Page 6: section v, lines 8 and 10, change "PIP products" to "Monsanto corn PIP products." Page 10, last line of 2nd paragraph, change "Monsanto PIP products" to "Monsanto corn PIP products".

Similarly on Page 12, section v, lines 7 and 10, change "PIP products" to "Monsanto corn PIP products."

In addition, we suggest the following editorial changes/correction:

- i. Page 9: point vi, change "April 30th" to "August 31st" to be consistent with point iv of Page 8. Also, on page 9, section a) Refuge Requirements for MON 89034 x MON 88017, third paragraph, change "MON 89034" to "MON 89034 x MON 88017".
- ii. Page 15: first paragraph of section e), correct typing error of "889034" to "89034". Also, on page 15, point vi, change "April 30th" to "August 31st" to be consistent with point iv of Page 8.

Per your request in the pre-acceptance letter, the following administrative materials are also provided herein:

- a) Updated labels for MON 89034 and MON 89034 x MON 88017
- b) Updated Confidential Statement of Formula (CSF)
- c) Updated Certification with Respect to Citation of Data Form
- d) Updated data matrix of MON 89034 and MON 89034 x MON 88017

If you have any questions regarding this letter and the attached materials please feel free to contact Dr. Russell Schneider, Senior Director, Monsanto Regulatory Affairs & Policy at (202) 383-2866, or me at the phone numbers or e-mail listed below.

Sincerely

Yong Gao, Ph.D.

Regulatory Affairs Manager

Monsanto Company

Office: (314) 694-2943 Mobile: (314) 488-0971 yong.gao@monsanto.com

cc: Susanne Cerrelli, EPA/OPP/BPPD Mike Mendelsohn, EPA/OPP/BPPD

8- Greet

Russell Schneider, Monsanto Carolyn Carrera, Monsanto

Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn (OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn......0.002-0.0056%

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 corn......0.0015-0.0055%

Percentage (wt/wt) on a dry weight basis whole plant (forage)

Caution

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS_____

EPA Registration No. 524-LTL

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. Information regarding commercial production must be included in the Technology Use Guide.

MON 89034 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers.

MON 89034 can be crossed with MON 88017 for breeding purposes to produce MON 89034 x MON 88017

In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.



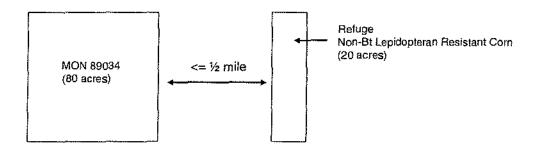
These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn and small scale research trials for observation, nor to commercial hybrid sweet corn.

For MON 89034 sweet corn, growers are required to destroy any MON 89034 sweet corn stalks that remain in the field following harvest via rotary mowing, discing, or plowdown within one (1) month of harvest.

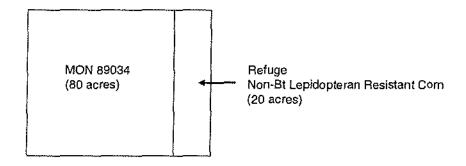
For MON 89034 field corn, grower guides must specify that growers must adhere to the following refuge requirements. Growers must plant a structured refuge of at least 20% corn which is not a lepidopteran-protected Bt corn. Growers who fail to comply with the IRM requirements risk losing access to Monsanto corn PIP products.

Refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), and strips across the field.

External refuges must be planted within ½ mile.



When planting the refuge in strips across the field, refuges must be at least 4 rows wide, preferably 6 rows wide.



Insecticide treatments for control of European corn borer, corn earworm, and Southwestern corn borer, cornstalk borer, sugarcane borer, fall armyworm and stalk borer may be applied only if economic thresholds are reached for one or more of these target

pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Instructions to growers will specify that microbial Bt insecticides must not be applied to non-Bt corn refuges.

Corn Insects Controlled

European corn borer Ostrinia nubilalis
Southwestern corn borer Diatraea grandiosella
Southern cornstalk borer Diatraea crambidoides
Corn earworm Helicoverpa zea
Fall armyworm Spodoptera frugiperda
Corn stalk borer Papaipema nebris
Sugarcane borer Diatreae saccharalis

Sales of corn hybrids that contain Monsanto's Bt corn plant pesticide must be accompanied by a Grower Guide which includes information on planting, production and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the Bt proteins is planted.

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents: 5023179, 5110732, 5164316, 5196525, 5322938, 5352605, 5359142, 5378619, 5424412, 6018100, 6051753, 6331665, 6489542, 6645497, 6962705, 7064249, and 7250501.



EPA Registration File No. 524-575 (Vol. 1).
Page is not included in this copy.
Pages 87 through 88 are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
X The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Enforcement sensitive information.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.
* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response tor reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

20460. Do not send the completed form to this address.	,,						
Certification with R	espect to Citation of	Data					
Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, (314) 694-2943	MO 63167	EPA Registration Number / File Symbol: 524-LTL					
Active Ingredient(s) and/or representative test compound(s): Bacilla	us thuringiensis	Date:					
Cry1A 105 and Cry2Ab2 Proteins and the Genetic I		May 7, 2008					
PV-ZMIR245) Necessary for their Production in M	ON 89034						
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name:					
Terrestrial field crop		MON 89034					
NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).							
I am responding to a Data-Call-in Notice, and have included to form should be used for this purpose).	with this form a list of companies	s sent offers of compensation (the Data Matrix					
Section I: METHOD OF DATA	SUPPORT (Check on	e method only)					
I am using the cite-all method of support, and have included this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	under the selec	selective method of support (or cite-all option ctive method), and have included with this form t of data requirements (the Data Matrix form					
Section II: GEN	ERAL OFFER TO PAY	/					
[Required if using the cite-all method or when using the cite-a	Il option under the selective me	thod to satisfy one or more data requirements]					
1 hereby offer and agree to pay compensation, to other person		ot this application, to the extent required by					
	CERTIFICATION						
I certify that this application for registration, this form for reregi- cited in the application for registration, the form for registration, or the I the selective method is indicated in Section 1, this application is suppo- this product or an identical or substantially similar product, one or more required to be submitted under the data requirements in effect on the d of a product of identical or similar composition and uses.	Data-Call-In response. In addition Inted by all data in the Agency's For the ingredients in this produ	on, if the cite-all option or cite-all option under files that (1) concern the properties or effects of ct; and (2) is a type of data that would be					
I certify that for each exclusive use study cited in support of thi have obtained the written permission of the original data submitter to ci		hat I am the original data submitter or that I					
I certify that for each study cited in support of this registration data submitter; (b) I have obtained the permission of the original da eligibility for compensation have expired for the study; (d) the study is the study and have offered (i) to pay compensation to the extent requegotiations to determine the amount and terms of compensation, if an	ta submitter to use the study in in the public literature; (e) I hav uired by sections 3(c)(1)(F) an	in support of this application; (c) all periods of e notified in writing the company that submitted d/or 3(c)(2)(B) of F/FRA; and (ii) to commence					
I certify that in all instances where an offer of compensation is in accordance with sections 3(c)(t)(F) and/or 3(c)(2)(B) of FIFRA are a produce such evidence to the Agency upon request, 1 understand that it product in conformity with FIFRA.	vailable and will be submitted to	the Agency upon request. Should I fail to					
I certify that the statements I have made on this form and at any knowingly false of misleading statement may be punishable b							
Signature	Date	Typed or Printed Name and Title					
28 60	May 7, 2008	Yong Gao, Ph.D. Regulatory Affairs Manager					

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of Information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX				
Date: May 7, 2008				EPA Reg. No	./File Symbol: 524-LTL	Page Lof 10
Ingredient Bacilfus thuring	Address: 00 N. Lindbergh Blvd., St. Louis, MO 6316 ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic		V-ZMIR245) Necessary		ION 89034 ction in MON 89034 (OE	CD Unique
Identifier: MON-89Ø34-3) Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
N/A	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bocillus thuringiensis Cryl A. 105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3).		Монзапто Сол	рацу	OWN	
885.1100	Bogdanova, N.N. 2006. Human Health and Environmentat Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cryl A. 105 and Cry2Ab2 Proteins Produced in Com MON 89034.	4695 (4-0)	Молѕано Сол	pany	Own	Product Characterization
885.1±00	Rice, J.F., B.J. Wolff, J.R, Groat, N.K. Scanton, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	469514-02	Monsanto Com	pany	own	Product Characterization
885.1100	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Com MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	4695†4-03	Mousanio Com	pany	own	Product Characterization
885.1100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovicli. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Mousanto Technical Report MSL-20071.	4695 t4-04	Молѕаньо Соп	pany	own	Product Characterization
Signature			Name and Title Yong Gao, Ph.D. Regulatory Affairs M		Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Streef, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX			
Date: May 7, 2008			[EF	A Reg. No./File Symbol: 524-LTL	Page 2 of t0
	00 N. Lindbergh Blvd., St. Louis, MO 631			oduct: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	: Material (Vector P	V-ZMIR245) Necessary for	their Production in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Nofe
885.1100	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E.Coli and Bt Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	4695 t4-05	Монѕал то Сотрану	y OWN	Product Characterization
885.1100	Rice, J.F., B.J. Wolff, f.C. Jennings, and J.D. Masiicci, 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Monsanto Technicat Report MSL-20068	466945-01	Mensanto Compan	y OWN	Product Characterization
885.1†00	Goertz, B., T. Ganguty, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the Cryt A.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.coli-Produced Cryt A.105 Proteins. Monsanto Technical Report MSL-19960.	466946-04	Monsanto Compan	y OWN	Product Characterization
	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular analysis of Corn MON 89034".	47 (275-03	Monsanto Compan	y OWN	Product Characterization
	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A. 105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials".	47†275-05	Mousanto Compan	y <u>O</u> WN	Product Characterization
Signature 4	8-0-8		Name and Title Yong Gao, Ph.D. Regulatory Affairs Mana	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

10 (10) 010 01, 0171, 1140111113011	, DC 20460. Do not send the form to this address.	TA MATRIX				
Date: May 7, 2008			· · · · · · · · · · · · · · · · · · ·	EPA Reg. N	lo./File Symbol: 524-LTL	Page 3 of 10
Applicant's/Registrant's Name &		· · · · · · · · · · · · · · · · · · ·				
Monsanto Company, 80	0 N. Lindbergh Blvd., St. Louis, MO 631	67		Product:	MON 89034	
Ingredient Bacillus thuringi Identifier: MON-89Ø34-3)	ensis Cry1A,105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Necessary	for their Prod	luction in MON 89034 (Ol	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cryt A.105 Protein to Cryt A Class of Boellius thuringiensis Proteins. Monsanto Technical Report 05-RA-62-01.	466946-01	Monsanto Com	pany	OWN	Product Characterization
860.1340	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Coni Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	466945-03	Monsanto Com	pany	OWN	Product Characterization
885.3050	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.	469514-0 6	Monsanto Com	pany	OWN	Human Health Assessment
885.1100	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	4695t4-07	Monsanio Coni	pany	OWN	Human Health Assessment
885.tt00	Kapadia, S. and E.A. Rice, 2005. Assessment of the in vitro Digestibility of the Cryt A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	469514-08	Monsanto Com	pany	NWO	Human Health Assessment
Signature 5	8-0-		Name and Title Yong Gao, Ph.D. Regulatory Affairs M	anager	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

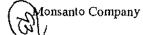




UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

40 t M Street, S.W., Washington	, DC 20460. Do not send the torm to this address.					
	DA	TA MATRIX				
Date: May 7, 2008				EPA Reg. No.	/File Symbol: 524-LTL	Page 4 of t0
Applicant's/Registrant's Name &					·····	<u></u>
	00 N. Lindbergh Blvd., St. Louis, MO 631				ON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	fensis CryIA.105 and Cry2Ab2 Proteins and the Genetic	c Material (Vector P	V-ZMIR245) Necessary f	or their Produ	ction in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1†00	MeCoy, R.L. and A. Sitvanovich. 2005. Bioinformatics Analysis of the CrytA.105 Protein Utilizing the AD5, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	466946-05	Monsanto Comp	any	OWN	Human Health Assessment
885.tt00	Thorp, J.J. and M.E. Goley. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938	4695 t4-09	Monsaulo Comp	any	OWN	Human Health Assessment
885.t100	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cryt A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-2035 t.	4695t4-t0	Monsanio Comp	any	OWN	Human Heatili Assessment
885.tt00	Kapadia, S.A. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the CrytA. 105 Protein in Simulated Gastrie Fluid. Monsanto Technical Report MSL-19929.	466946-06	Monsanto Comp	eany	OWN	Human Health Assessment
885.1100	Goley, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and CrytA.105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technicat Report MSL 19899.	466946-07	Mousanto Comp	any	OWN	Human Health Assessment
885.3050	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with Cryt A. 105 Protein. Monsanto Study CRO-2005-050.	466946-03	Monsanto Comp	oany	OWN _	Human Health Assessment
Signature	28 Cere		Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma	nager	Date May 7, 2008	



\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.	TA MATRIX	<u></u>	·····	
Date: May 7, 2008	<u> </u>	IA WAIRIA		PA Reg. No./File Symbol; 524-LTL	Page 5 of t0
Applicant's/Registrant's Name &	Address: 00 N. Lindbergh Blvd., St. Louis, MO 631	 67		roduct: MON 89034	
	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic				CD Unique
Guideline Reference Number	Guideline Study Name	MR(O Number	Submitter	Status	Note
885.t t00	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	4695†4-††	Мопзапто Сотрап	y OWN	Human Health Assessment
885.4050	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Controt or Commercial Com. Monsanto Study 05-01-50-13, Amended Report.	469 51 4-t2	Monsanto Compan	y OWN	Human Health Assessment
N/A	MacRae, T.C., C.R. Brown, and S.L. Levinc. 2006. Spectrum of Insecticidal Activity of Bacillus thuringlensis Cryll A. 105 Protein. Monsanto Technical Report MSL- 20230.	4695†4-†3	Monsanto Compan	y OWN	Environinchtal Assessment
N/A	MacRac, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.	4695†4- † 4	Monsanio Compan	y OWN	Environmental Assessment
N/A	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Com MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.	4695†4-†5	Monsanto Compan	ıy OWN	Environmental Assessment
Signature	2-2-		Name and Title Yong Gao, Ph.D. Regulatory Affairs Mana	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.	TA MATRIX		····	
Date: May 7, 2008		IA WAINIA		EPA Reg. No./File Symbol: 524-LTI	Page 6 of 10
	00 N. Lindbergh Blvd., St. Louis, MO 631			Product: MON 89034	
Ingredient Baciflus thuring Identifier: MON-89Ø34-3)	iensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	: Material (Vector PV	V-ZMIR245) Necessary fo	or their Production in MON 89034 (C	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (Fofsomia candida). Monsanto Technical Report MSL-20169.	4695 4-16	Monsanto Compa	any OWN	Environmentat Assessment
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran Daphaia magna: An acute static-renewal test with compollen. Monsanto Study WL-2005-0tt.	4695t4-t7	Мопзалю Сопр	any OWN	Environmentat Assessment
885.6200	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cryt A. 105 Protein in an Acute Study with the Earthworm in an Artificial Soit Substrate. Monsanto Technical Report MSL-20147.	4695 t4-18	Monsanto Comp	any OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cryt A.105 Protein on Honeybee Larvae (Apis mellifera L.). Monsanto Study CA-2005-07t.	4695 t4-t9	Monsanto Comp	any OWN	Environmental Assessment
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cryt A. t05 Protein on Adult Honeybees (Apis mellifera L.). Monsanto Study CA-2005-072	4695 t4-20	Мопsanto Comp	any OWN	Environmental Assessment
Signature	97) Electronic and Paner versions available. Submit only		Name and Title Yong Gao, Ph.D. Regulatory Affairs Man	<u></u>	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary torms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washingtor	t, DC 20460. Do not send the form to this address.			· · · · · · · · · · · · · · · · · · ·		
	DA	ATA MATRIX				
Date: May 7, 2008	Date: May 7, 2008					Page 7 of t0
Applicant's/Registrant's Name 8			<u></u>	,-u		
Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 631	167	\	Product: M	ION 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Genet	tic Material (Vector)	PV-ZMIR245) Necessary	for their Produ	iction in MON 89034 (6	OECD Unique
Guideline Reterence Number	Guideline Study Name	MRIO Number	Submitter		Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cryt A.105 Protein on the Ladybird Beetle, Coleomegitta maculara (Coleoptera: Coceinellidae). Monsanto Technical Report MSL-20150.	469514-2†	Monsanto Com	pany	OWN	Environmental Assessment
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Coleannegilla maculana (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.	4695 14-22	Monsanto Com	pany	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cryt A. 105 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthecoridae). Monsanto Technical Report MSL-20170.	469514-23	Monsauto Com	рапу	OWN	Environmental Assessment
885.4340	Teixeira, D. 2006. Evaluation of Potential Dictary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemi ptera: Anthocoridae). Monsanto Teelmical Report MSL-2017t.	469514-24	Monsanto Con	ipany	OWN	Environmental Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cryt A.105 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae). Monsanto Technicat Report MSL-20149.	4695 4-25	Monsanto Con	ipany	OWN	Environmental Assessment
Signature	28-Ce		Name and Title Yong Gao, Ph.D. Regulalory Affairs Ma	nager	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



ŞEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary lorms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	information, including suggestions for reducing the burde i, DC 20460. Do not send the form to this address.				oteotion Agency,
	DA	TA MATRIX	·		<u>,</u>
Date: May 7, 2008			EP	A Reg. No./File Symbol: 524-LTL	Page 8 of 10
Applicant's/Registrant's Name &					
Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 631	67	Pro	oduct: MON 89034	
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Genet	ic Material (Vector P	V-ZMIR245) Necessary for	their Production in MON 89034 (C	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gattagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.	469514-27	Monsanio Company	OWN	Environmental Assessment
885.5200	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, f. Murphy, S. Levine, J. Hottmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.	4695†4-28	Monsanto Company	OWN	Environmentat Assessment
N/A	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.	469514-29	Monsanto Company	, OWN	Environmentat Assessment
N/A	MacRac, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Bocillus Timringiensis Proteins Cry1A.105 and Cry2Ab2. Monsanto Tecimical Report MSL-19859.	466946-02	Monsanto Company	OWN	Environmentat Assessment
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.	4695 14-26	Monsanto Company	OWN	Environmentai Assessment
Signature	-8 Cro-		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manag	منطنته والمستحدد المنات والمستحدد والمستحدد والمستحدد والمستحد والمستحدد والمستحدد والمستحدد والمستحدد والمستحدد	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Streel, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	TA MATRIX				····
Date: May 7, 2008			g de la companya de l	EPA Reg. No./F	File Symbol: 524-LTL	Page 9 of 10
Applicant's/Registrant's Name &	Address:					
	00 N. Lindbergh Blvd., St. Louis, MO 631				ON 89034	
Ingredlent <i>Bacillus thur</i> ing Identifier: MON-89Ø34-3)	giensis Cryl A.105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector F	V-ZMIR245) Necessary	for their Produc	tion in MON 89034 (OI	ECD Unique
Guideline Reterence Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885 4340	Palmer, S.J. and H.O. Krueger. 2000. Insect Protection Protein 2: An Acute Toxicity Study With the Earthworm in an Artificial Soif Substrate. Monsanto Technical Report MSL-16177	450863-13	Monsanto Comp	any	OWN	Environmental Assessment
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified Bacillus thuring iensis Cry2Ab2 protein on honey bee tarvae. Monsanto Technical Report MSL-16961.	4 5 3371-02	Мопsanto Comp	any	OWN	Environmental Assessment
885,4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Coltembola (Folsomia candida), Amended report. Monsanto Technical Report MSL-16174.	450863-14	Monsanto Com	oany	OWN	Environmental Assessment
885,4340	Patmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dictary Toxicity Study with Parasitic Hymenoptera (Nasonia vitripennis). Monsanto Technical Report MSL-16173.	450863- 1 0	Monsanto Comp	oany	OWN	Environmentat Assessment
885.4380	Maggi, V.L. 2000. Evaluation of the Dictary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technical Report MSL-16176.	450863-08	Monsauto Comp		OWN	Environmental Assessment
Signature 2	8-6-0		Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma	<u>, </u>	Oate May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



≎EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2 t37), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

40t M Street, S.W., Washington	, DC 20460. Do not send the form to this address.		····		
	DA	TA MATRIX			
Date: May 7, 2008			E	PA Reg. No./File Symbol: 524-LTI	Page 10 of t0
	0 N. Lindbergh Blvd., St. Louis, MO 631			Product: MON 89034	
Ingredient Baciflus thuring Identifier: MON-89Ø34-3)	tiensis Cry1A.105 and Cry2Ab2 Proteins and the Geneti	ic Material (Vector P	V-ZMIR245) Necessary fo	r their Production in MON 89034 (OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
N/A	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Com, MON 89034. Monsanto Teclinical Report 06-RA-39-06.	4695†4-30	Monsanto Compar	ıy OWN	IRM
	Bogdanova, N. and A. Crawford (2007). Public Interest Document Supporting Registration of Bacillus thuringiensis Cryl A. 105, Cry2 Ab2 and Cry3 Bb1 Proteins in Insect-Protected Com MON 89034 and MON 89034 x MON 88017		Monsanto Compa	ıy OWN	Benefits
	Bogdanova, N., S. Dubelman, M. Mucth, J. Murphy and A. Silvanovich (2007). Responses to EPA Questions Regarding Application 524-LTL to register Insect- Protected Corn MON 89034 (MRID 46951428)	47t403-0t	Mousanto Compa	ny OWN	Misc.
	Bogdanova, N., (2007) Responses to EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 4695 1400 and 4695 1300)	471275-01	Monsanto Compa	ny OWN	Misc.
	Bogdanova, N (2007). Supplemental Information 10 Address EPA Questions Regarding Applications 524-LTL and 524-LTL to Register Insect-Protected Com MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	470794-02	Monsanto Compa	ny OWN	Misc.
Signature	-8		Name and Title Yong Gao, Ph.D. Regulatory Affairs Man		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street S.W. Washington DC 20460. Do not send the form to this address.

401 M Street, S.W., Washingtor	information, including suggestions for redu n, DC 20460. Do not send the form to this a	icing the burden to: Director, OPPE ink address.	ormation imanagement Division (2	(37), U.S. Environmental Pro	nection Agency,
	······································	DATA MATRIX			
Date: May 7, 2008			EPA Reg. i	No./File Symbol: 524-LTL	Page t of 10
Applicant's/Registrant's Name &					· · · · · · · · · · · · · · · · · · ·
	00 N. Lindbergh Blvd., St. Loui			MON 89034	Eco II.
Ingredient Bacillus thurin Identifier: MON-89Ø34-3)	grensis Cry1A.105 and Cry2Ab2 Proteins	and the Genetic Material (Vector PV-	ZMIK245) Necessary for their Pr	oduction in MON 89034 (O.	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
				1	
			Monsanto Company	OWN	
				ļ	
			Mensanto Company	OWN	Product Characterization
					
					Product
		-	Monsanto Company	OWN	Characterization
				1	
				ĺ	Product
			Monsanto Company	OWN	Characterization
					Product
		<u> </u>	Monsanto Company	OWN	Characterization
Signature			Name and Title	Date May 7, 2008	
5	- J - C -		Yong Gao, Ph.D.	Way /, 2006	
			Regulatory Affairs Manager		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington, DC 20460. Do not send the form to this addre	DATA MATRIX	······································		
	DATA MATRIX			
Date: May 7, 2008		EPA Re	g. No./File Symbol: 524-LTL	Page 2 of t0
Applicant's/Registrant's Name & Address:				
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, N		Product		
ingredient Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins and t Identifier: MON-89Ø34-3)	hc Genetic Material (Vector PV-2	ZMIR245) Necessary for their	Production in MON 89034 (O.	ECD Unique
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company	OWN	Product Characterization
		Monsanto Company	OWN	Product Characterization
		Monsaulo Company	OWN	Product Characterization
		Monsanto Company	own	Product Characterization
		Молѕащо Сотрапу	own	Product Characterization
Signature 58	}	Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



©EPA

Form Approved OMB No. 2070-0060

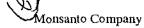
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	, DC 20460. Do not send the form to this ac	ddress.	······································		
		DATA MATRIX			
Date: May 7, 2008			EPA Reg. 1	No./File Symbol: 524-LTL	Page 3 of t0
Applicant's/Registrant's Name & Monsanto Company, 80	Address: 00 N. Lindbergh Blvd., St. Louis	s, MO 63167	Product:	MON 89034	
	riensis Cry1A.105 and Cry2Ab2 Proteins a		-ZMIR245) Necessary for their Pro	oduction in MON 89034 (Ol	CD Unique
Guideline Reterence Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsaulo Company	OWN	Product Characterization
			Monsanto Company	OWN	Produci Characterization
			Monsanto Company	OWN_	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
			Monsanto Company	OWN	Human Health Assessment
Signature	97) Electronic and Paner versions available		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



©EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden lo: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	n, DC 20460. Do not send the torm to this address.	TA MATRIX				
D. J. May 7, 2009				EDA Boo Na	/File Symbol; 524-LTI	Page 4 of 10
Date: May 7, 2008 Applicant's/Registrant's Name 8	Address			EFA Reg. NO	77File 3yi7ib0i, 324-1311	J rage + or to
	00 N. Lindbergh Blvd., St. Louis, MO 631	167		n M	ION 89034	
	giensis CryIA.105 and Cry2Ab2 Proteins and the Genel		/ 7MID245) N			OPOD Hairman
Identifier: MON-89Ø34-3)	giensis Cty14.103 and Cry2A02 Proteins and the Gener	ne maieriai (vector P	v-Ziviik245) Necessary	ior meir Prod) PCOCO III IVIOIV 85054 (OECD Chique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
Management National Participation	E CONTROL OF CONTROL	All the transfer				
				ļ		Human Health
			Monsanto Comp	anv	OWN	Assessment
				······		
				ŀ		Ì
						Human Health
			Monsanio Company		OWN	Assessment
				Ì		Human Health
			Monsanto Comp	yany (OWN	Assessment
			MOI SERIO COM	<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>		
						Human Health
			Monsanto Comp	oany	OWN	Assessment
						Human Health
			Monsanto Comp	any	OWN	Assessment
						Human Health
			Monsanto Comp	nanv	OWN	Assessment
Signature					Date	
Signature (Name and Title		May 7, 2008	
 _	18 00		Yong Gao, Ph.D.		11111 /, 2000	
			Regulatory Affairs Ma		<u> </u>	
EDA Form 0570 05 (0)	97) Electronic and Paper versions available. Submit only	Danor voveion	Puli	Ilc File Copy	,	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

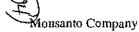
Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per

·	DATA MATRIX			
ate: May 7, 2008		ļ ļ E	PA Reg. No./File Symbol: 524-LT	L Page 5 of 10
pplicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St.	Louis, MO 63167		roduct: MON 89034	— <u> </u>
ngredient Bacitlus thuringiensis Cry I A, 105 and Cry 2 Ab 2 Predentifier: MON-89Ø34-3)	roteins and the Genetic Material (Vector PV	-ZMIR245) Necessary fo	r their Production in MON 89034	(OECD Unique
Guideline Reference Number Guideline Study Name	MRID Number	. Submitter	Status	Note
		Monsanio Compan	y OWN	Human Health Assessment
		Monsanto Compan	y OWN	Human Health Assessment
		Monsanto Compan	y OWN	Environmenta Assessment
		Monsanto Compar	ıy Own	En vironmental Assessment
		Monsanto Compar	ay OWN	Environniental
Signature	9	Name and Title Yong Gao, Ph.D. Regulatory Affairs Mana	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response tor reregistration and special review activities, including time for reading the instructions and completing the necessary torms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, DPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

40t M Street, S.W., Washington	, DC 20460. Do not send the form to this address	ss.		Division (2137), 0.3. Environmental	
		DATA MATRIX	- 		
Date: May 7, 2008				EPA Reg. No /File Symbol: 524-LT	L Page 6 of t0
Applicant's/Registrant's Name &					
	00 N. Lindbergh Blvd., St. Louis, M		l	Product: MON 89034	· · · · · · · · · · · · · · · · · · ·
Ingredient Bacillus rhuring Identifier: MON-89Ø34-3)	glensis Cry1A.105 and Cry2Ab2 Proteins and t	he Genetic Material (Vector PV	-ZMIR245) Necessary	for their Production in MON 89034	(OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Comp	any OWN	Environmental Assessment
			Monsanto Comp	any OWN	Environmental Assessment
			Monsanto Comp	oany OWN	Environmental Assessment
			Monsanto Comp	oany OWN	Environmental Assessment
			Молsanto Сопц	oany OWN	Environmental Assessment
Signature	7-8-00		Name and Title Yong Gao, Ph.D. Regulalory Affairs Ma	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



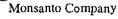
\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary torms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX				
Date: May 7, 2008				EPA Reg. No./	File Symbol: 524-LTL	Page 7 of t0
Applicant's/Registrant's Name &						
Monsanto Company, 80	00 N. Lindbergh Blvd., St. Louis, MO 6	53167	f.	Product: MC		
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	ensis Cryl A.105 and Cry2Ab2 Proteins and the Ger	uctic Material (Vector PV-2	ZMIR245) Necessary fo	or their Produc	tion in MON 89034 (OE	CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
			Monsanto Comp	any	OWN	Environment at Assessment
			Monsanto Comp.	any	OWN	Environmentat Assessment
		_	Моиsanto Comp	any	оwи	Environmentat Assessment
			Monsanio Comp	any	OWN	Environmental Assessment
			Monsanto Comp	any	OWN	Environmental Assessment
Signature S	97) Electronic and Paner versions available Suhmit	1	Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma	Ì	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary torms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washinglor	n, DC 20460. Do not send the form to this address.	·····			<u></u>	
	D.	ATA MATRIX	<u></u>			····
Date: May 7, 2008			e de la companya de l	EPA Reg. No./	File Symbol: 524-LTI	L Page 8 of 10
Applicant's/Registrant's Name &						
Monsanto Company, 8	00 N. Lindbergh Blvd., St. Louis, MO 63	167		Product: MC		
Ingredient Bacillus thurin Identifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Gene	etic Material (Vector P	V-ZMIR245) Neccssary f	or their Produc	ction in MON 89034 (OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
			Monsanto Compa	any	<u>own</u>	Environmental Assessment
			Monsanto Сопра	any	own	Environmental Assessment
			Monsanto Comp	any	<u>OWN</u>	En vironmentat Assessment
			Monsanto Comp	anv	<u>OWN</u>	Environmental Assessment
			Monsanto Comp		own	Environmental Assessment
Signature	-8 C-e		Name and Title Yong Gao, Ph.D. Regulatory Affairs Ma	<u> </u>	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



SEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Intormation Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
ate: May 7, 2008			EP	A Reg. No./File Symbol: 524-LT	L Page 9 of t
pplicant's/Registrant's Name &	Address:				,t,
	00 N. Lindbergh Blvd., St. Louis, MO 63			oduct: MON 89034	
gredient Bacillus thuring icutifier: MON-89Ø34-3)	giensis Cry1A.105 and Cry2Ab2 Proteins and the Gen	etic Material (Vector PV-	ZMIR245) Necessary for	their Production in MON 89034	(OECD Unique
uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Мопѕаню Сотрапу	OWN	Environments Assessment
			Monsanto Company	OWN	Environments Assessment
			Monsanto Company	OWN	Environment Assessment
			Monsanto Company	OWN	Environment Assessment
			Monsanto Company	OWN	Environment Assessment
Signature \bigcirc	e & &		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manag	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities including time for reading the instructions and completing the necessary forms. Send competits recording the burden estimate or any

	n, DC 20460. Do not send the form to this add	DATA MATRIX			
Date: May 7, 2008			EPA Re	g. No./File Symbol: 524-LTL	Page t0 of t0
Applicant's/Registrant's Name	& Address: 000 N. Lindbergh Blvd., St. Louis,	Product	Product: MON 89034		
	ngiensis CryIA.105 and Cry2Ab2 Proteins and		ZMIR245) Necessary for their	Production in MON 89034 (OI	ECD Unique
Guideline Reference Number	Guideline Study Name	MR(D Number	Submitter	Status	Note
			Мопѕапіо Сопрапу	OWN	IRM
		_	Mousanto Company	own	Benefits
		_	Monsanio Company	OWN	Misc.
			Monsanio Company	OWN	Misc.
			Mousanto Company	own	Misc.
Signature	LA QQ		Name and Title Yong Gao, Ph.D. Regulatory Affairs Manager	Date May 7, 2008	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



DEC 1 9 2007

OPP Decision Numbers:

D-371 t89

D-371190

Yong Gao Regulatory Affairs Manager Monsanto Company 1300 I Street, NW Suite 450 East Washington, DC 20005

Dear Dr.Gao:

Subject: MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and

MON89034 (Cry1A.105, and Cry2Ab2) Corn EPA Petition Numbers: 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL Application Date: September 29, 2006 EPA Receipt Date: September 29, 2006

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008.

Our review of your public interest document is ongoing. Provided that we are able to determine the registration of these products would be in the public interest, that you make the following changes to your proposed insect resistance management (IRM) refuges, and that you drop the proposed popcorn use, the Agency will be able to continue processing your applications.

If you choose not to modify the IRM refuge proposals and drop the popcorn use, the applications will be deemed incomplete. Within seventy-five (75) days, please indicate whether you will modify the IRM refuges and drop the popcorn use, and submit in writing a commitment to perform the required data listed below.

The Agency is requesting the following revisions to your proposed IRM refuges. Please consult the enclosed data evaluation records for detailed information.

GONCURRENCES								
SYMBOL >	7511	7511P	75111'A	hsif.				
SURNAME >	north	Regnolds	Storik	Rull				
DATE -	19/1407	12/18/07	12/14/17	12/19/07				(110)
EPA Form 1	320-1A (1/90)		P	rinted on Recycled	Paper		OFFIC	AL FILE COP

REVISED IRM REFUGES

MON 89034 field corn uses in the corn belt including the separate refuge for 89034 x 88017.

- (1) Pyramids can reduce the need for large refuges. Monsanto has proposed that a 5% structured refuge, rather than the current 20% structured refuge, be used with the field corn uses of MON 89034. However, Monsanto's data and modeling <u>do not</u> support a 5% structured refuge for MON 89034 for field corn uses in the Corn Belt. A 20% structured refuge requirement for field corn uses of MON 89034 in the Corn Belt can be supported at the present time.
- (2) <u>MON 89034 field corn use in cotton-growing areas.</u> A 20% non-Bt corn refuge for MON 89034 in the southern cotton-growing areas would be sufficient to manage the risk of resistance evolution to Bt corn and Bt cotton products <u>assuming there is no cross-resistance</u>. Refer to sections (3) and (4) below.

The following data deficiencies must be addressed post-registration to support a conditional registration with the above mentioned revised 20% non-Bt IRM refuges and no popcorn use sites.

DATA REQUIRED POST-REGISTRATION WITH REVISED IRM REFUGES

- (1) For event MON 89034 corn and event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 is needed.
- (2) <u>Freshwater aquatic invertebrates for MON 89034 (MRID 469514-17)</u>
 The *Daphnia magna* study is unacceptable because the 48 hour test duration is not sufficient to show mortality for Bt toxins. It takes more than 48 hours for the target pests to succumb to the Cry proteins therefore 48 hours is also too short to show mortality to *Daphnia*. A 21 day daphnia study, as outlined in the OPPTS Microbial Test Guidelines, needs to be performed. The study may be submitted as a condition of registration.
- (3) Monsanto did not address the likelihood of cross-resistance of Cry1A.105, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.
- (4) Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of

MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.

- (5) Monsanto is reminded that to support the sweet corn use site, a grower guide must be distributed to all customers using seed containing the plan-incorporated protectant that will include instructions and recommendations regarding product use, insect resistance management and integrated pest management. The following information regarding commercial productions must be included in the Grower guide:
 - Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
 - The allowed crop destruction methods are rotary mowing, discing, or plow-down.
 Crop-destruction methods should destroy any surviving resistant insects.

If Monsanto chooses to register their products with a 5% structured refuge the following additional data are required.

DATA REQUIRED TO SUPPORT MON 89034 FIELD CORN USES IN THE CORN BELT WITH A 5% STRUCTURED REFUGE:

Monsanto must address the uncertainties in the dose determination for ECB, SWCB, CEW, FAW (SS and RS mortality), cross-resistance likelihood of Cry1A.105, Cry1Ac, and Cry1Fa and its impact on the durability of MON 89034, and limitations of the simulation modeling. Please also refer to the enclosed review for a full discussion of BPPD's analysis of the IRM plan for MON 89034.

- a) <u>Dose determination.</u> Monsanto relies on the Roush (1998) model to support the need for a 5% structured refuge rather than a 20% structured refuge in the Corn Belt. Roush's model (1998; Figure 2) indicates that a 5% structured refuge is equal to or greater than a 20% structured refuge for a highly effective, high dose single-gene product when a two-gene product (MON 89034 in this case) achieves at least 95% control of susceptible homozygotes <u>and</u> 70% control of heterozygotes assuming there is no cross-resistance. The dose information provided by Monsanto is not sufficient to demonstrate that each protein will kill 95% of the homozygous susceptible insects and 70% of the heterozygotes. BPPD recommends that Monsanto further investigate whether MON 89034 consistently has high mortality of susceptible homozygotes (>95%) and whether the heterozygote mortality is at least 70% for MON 89034 against the target pests (for the Corn Belt ECB and SWCB). The 1998 SAP suggested several ways to estimate mortality for less susceptible larvae (i.e. heterozygotes) (EPA 1998). These techniques included testing larger, later instar larvae that may be less susceptible.
- b) <u>Cross Resistance</u>. Additional information is needed on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (including binding site models and use of resistant colonies) for the target pests and a determination of how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It



is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.

c) <u>Modeling</u>. Additional species-specific (e.g, ECB and SWCB for the Corn Belt), spatially-explicit, landscape modeling is needed to explore the durability of MON 89034 versus single-protein Bt corn products. Modeling should consider the impact of other Bt proteins in the landscape that may confer some cross-resistance (to Cry1A. t05, in particular) and how such cross-resistance would impact the durability of MON 89034 in the Corn Belt (i.e., the use of simulation modeling). This is analogous to the species-specific simulation modeling that EPA required Monsanto do to support the use of natural refuge (instead of a structured refuge) for management of *H. virescens* and *H. zea* to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II cotton.

If you do not modify your refuge proposals as described above, the application will be deemed deficient.

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

Based on the content and timing of your response, the PRIA date for these applications may need to be renegotiatied. Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,

Sheryl Reifly, Chief

Microbial Pesticides Branch' Biopesticides and Pollution

Prevention Division (7511P)



Sharlene Matten/DC/USEPA/US 07/23/2007 02:50 PM To Alan Reynolds/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

 ∞

bcc

Subject Attachments: MON 89034: IRM and Benefits studies plus comments on Public Interest Finding, sweet corn and popcorn uses

Forgot the attachment, SRM

Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514

----Forwarded by Sharlene Matten/DC/USEPA/US on 07/23/2007 02:51PM -----

To: Susanne Cerrelli/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA

From: Sharlene Matten/DC/USEPA/US

Date: 07/23/2007 02:46PM

Subject: MON 89034: IRM and Benefits studies plus comments on Public Interest Finding,

sweet corn and popcorn uses

Susanne -- I extracted, from an earlier table you sent to me, all of the IRM and efficacy and insect spectrum studies that Alan and I are reviewing. We are doing the IRM Plan review together. I am doing all of the efficacy and insect spectrum studies. I did not have all of the Submission information in all cases.

I do not have any document that would be used to make a Public Interest Finding should there be a conditional registration under 3(c)7(C). I would not assume that registration of MON 89034 will be an unconditional 3(c)5 registration; therefore, we need to make a Public Interest Finding and have a document from Monsanto that gives us the appropriate information to make such a finding.

In addition, we do not have sufficient information (expression and activity) to complete an IRM assessment for sweet corn. We have no information on popcorn. My recommendation is that Monsanto withdrawal both the sweet corn and popcorn uses until such information can be generated and submitted to EPA to support these uses

Sharlene Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514



IRM and Benefil studies.doc



Natalia N. Bogdanova, D.V.M. Regulatary Affairs Manager (314)-694-3143 MONSANTO COMPANA
800 NORTH LINOBERGH 8EVO
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

May 25, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Response to questions from EPA regarding insect-protected corn MON 89034

EPA File Symbol 524-LTL

Dear Dr. Reilly:

Subject:

This letter is in response to the Agency's request from May 16, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn product MON 89034.

Responses to the Agency's questions are included in Volume 2 of this submission. This submission includes documents that have been classified as 'A'- non-confidential documents that can be released to the public. A pdf file is included.

Volume	Document	Category	Hard copy	pdf. file for E-docket
N/A	Cover Letter	A	. √	V
N/A	Transmittal Document	A	√	√
\$ Proof	Administrative Materials for Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951400)	A	. 1	1
2	Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951400)	A	√	√

}

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Allender Burger

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD

Russell Schneider, Monsanto Monsanto Regulatory Files

(116)



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005



Administrative Materials for the Registration of Insect-protected Corn MON 89034 (EPA File 524-LTL)

TRANSMITTAL DATE

May 25, 2007

MONSANTO REFERENCE No.

06-CR-172-4

177

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1.	Administrative Materials for the Response to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034					
	(MRID 46951428)					
		7 7 3 7 3 8 3 3				
	MRID Number)				
Volume 2.	Responses to EPA Questions Regarding Application 524-LTL Insect-protected Corn MON 89034 (MRID 46951428)	to Register				
	MRID Number					

Company Official: May 25, 2007

Natalia N Bogdanova, D.V.M.

Date

Regulatory Affairs Manager

(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Director, Regulatory Affairs

(202) 383-2866





Title

Administrative Materials for the Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951428)

Author

Natalia N. Bogdanova, D.V.M.

Submission Date

May 25, 2007

Submitting Registrant

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005

Registrant Reference No.

06-CR-172-4

Volume 1 of 2

Monsanto Company 06-CR-172-4 Page 1 of 7

TABLE OF CONTENTS

Table of Contents	2
Administrative Materials	3
Application for Registration (Form 8570-1)	4
Certification with Respect to Citation of Data (Form 8570-34)	5
Data Matrix (Form 8570-35)	6

ADMINISTRATIVE MATERIALS

Application to Register (Form 8570-1)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

Monsanto Company 06-CR-172-3 Page 3 of 7



Ptease read instructions on re	everse before completing form.	Form Approved, OMB No. 207	0-0060. Approval Expires 2-28-95				
ŞEPA	United State Environmental Prote Washington, DC	es United Section Agency 20460	Registration OPP Identifier Number Amendment Other				
	Application for I	Pesticide – Section I					
1. CompanytProduct Number File Syml	ool 524-LTL	EPA Product Manager Sheryl Reilly Sheryl Reilly 3. Proposed Classification of the state of t					
Company/Product (Name) MON	89034	PM# 92	None Restricted				
5. Name and Address of Applicant (for Monsanto Company 1300 I (Eye) Street, N.W., Sur Washington, DC 20005		6. Expedited Review. In accordant product is similar or identical in compose EPA Reg. No. Product Name					
	Sec	tion – II	· · · · · · · · · · · · · · · · · · ·				
Notification – Explain Explanation: Use additional page(s	onse to Agency tetter dated pelow.) if necessary. (For Section I and Sec	Final printed labels in Agency letter dated "Me Too" Application, Other – Explain below tion II.) tion to register insect-protected co.	,				
	Sec	tion – III					
Material This Product Will Be Pa Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No No If "Yes" No. per Unit Packaging wgt. Container	Yes No If "Yes" No. per Package wgt. Container (S)	Type of Container Metal Plastic Glass Daper Other				
3. Location of Net Contents Information Label Container		On On	on of Label Directions Label Labeling accompanying product				
o. Manner in Which Label is Affixed to	p. Manner in Which Label is Affixed to Product Lithograph Other Paper glued Stenciled						
t Contact Point (Complete Hame disco		tion – IV If to be contacted, if necessary, to process	this application)				
Name	Title	a to be contacted, if necessary, to process	Telephone No. (tnctude Area Code)				

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

Russell P. Schneider

both under applicable taw.

Natalia N. Bogdanova

2. Signature

4. Typed Name

White - EPA File Copy (original)

Director, Regulatory Affairs

Regulatory Affairs Manager

May 25, 2007

Yeltow - Applicant Copy

(202) 383-2866

6. Date Application

Received

(Stamped)



Monsanto Company 06-CR-172-3 Page 4 of 7

Certification

3. Title

5. Date

I certify that the statements I have made on this form and alt attachments thereto are true, accurate and complete.

I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or

Tel. (314) 694-3143

₩EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460.

burden to Director, OPPE Information Management Division (2137), U.S. Do not send the completed form to this address.	S. Environmental Protection Ag	gency, 401 M Street, S.W., Washington DC, 20460.					
Certification with F	Respect to Citation of	f Data					
Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbot:						
Monsanto Company, 1300 I (Eye) Street, N.W., Washington, D	OC 2005 (202) 383-2866	524-LTL					
Active Ingredient(s) and/or representative test compound(s): Bf Cry1A. and the genetic material (vector ZMIR245) necessary for its productio		Date: May 25, 2007					
General Use Pattem(s) (list all those claimed for this product using 40 0	OFR Part 158:	Product Name:					
Terrestrial field crop		MON 89034					
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption	Statement (EPA Form 8570-2	7)					
I am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of companies	s sent offers of compensation (the Data Matrix form					
Section I: METHOD OF DA	TA SUPPORT (Check of	one method only)					
t am using the cite-all method of support, and have included w this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).							
Section II: GEI	NERAL OFFER TO PA	Υ					
[Required if using the cite-all method or when using the cite-all	l option under the setective me	thod to satisfy one or more data requirements[
I hereby offer and agree to pay compensation, to other person	s, with regard to the approval o	of this application, to the extent required by FIFRA.					
	I: CERTIFICATION						
the application for registration, the form for registration, or the Data-Cal method is indicated in Section 1, this application is supported by all dat an identical or substantially similar product, one or more of the ingredie	I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or						
t certify that for each exclusive use study cited in support of the obtained the written permission of the original data submitter to cite that		that I am the original data submitter or that I have					
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.							
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FtFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FtFRA.							
t certify that the statements t have made on this form and al knowingly false of misleading statement may be punishable by fin							
Signature	Date	Typed or Printed Name and Title					
the first the second of the second	May 25, 2007	Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager					

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any otter aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA MATRIX			
Date: May 25, 2007 Applicant's/Registrant's Name & Address: Monsauto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005			EPA Reg. No./File Symbol: 524-LTL	
			Product: MON 89034	
		Submitter	Status	Note
Volume 1. Administrative Materials for the Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034(MRID 46951428)		Monsanto Company	own	This Submission
Volume 2. Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951428)		Monsanto Company	OWN	This Submission
Land of the state		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date May 25, 2007	
	Address: (Eye) Street, N.W., Suite 450 East, Washington, glensis CryIA.105 and Cry2Ab2 and the genetic and Guideline Study Name Volume 1. Administrative Materials for the Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034(MRID 46951428) Volume 2. Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951428)	Address: (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005 Gensis CryIA.105 and Cry2Ab2 and the genetic material necessary Guideline Study Name MRID Number	EPA Reg. No./File Symbol Address: (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005 Product: MON 89034 Product: MON 89	EPA Reg. No./File Symbol: 524-LTL Address: (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005 Product: MON 89034 Stensis CryIA.105 and Cry2Ab2 and the genetic material necessary for their production (vector ZMIR245) in MON 89034 Guideline Study Name WRID Number Volume 1. Administrative Materials for the Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034(MRID 46951428) Wolume 2. Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951428) Monsanto Company OWN Name and Title Natalia N. Bogdanova, D.V.M. May 25, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street S.W. Washington, DC 20460. Do not send the form to this address.

DATA MATRIX			
	EPA Reg. No./File Sy	mbol: 524-LTL	Page I of I
Slington D.C. 20005			
			N 89034
MRID Number	Submitter	Status	Note
	Monsanto Company	OWN	This Submission
	Monsanto Company	OWN	This Submission
	Nome and Title	D-1-	<u>l</u>
^	Natalia N. Bogdanova, D.V.M.	May 25, 2007	
	Shington, D.C. 20005 us and the genetic material nec	EPA Reg. No./File System of the second state o	EPA Reg. No./File Symbol: 524-LTL Shington, D.C. 20005 Product: MON 89034 us and the genetic material necessary for their production (vectors ZMIR245) in MOI MRID Number Submitter Monsanto Company OWN Monsanto Company OWN Name and Title Date

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.







"SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@m onsanto.com>

05/14/2008 04:17 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

CC Sheryl Reilly/DC/USEPA/US@EPA

bcc

Subject CFIA discussion

History:

This message has been forwarded.

Mike/Susanne,

Please accept this email as Monsanto's agreement for EPA to discuss the

registration of MON 89034 insect protected corn with CFIA. I am sure

you will hear questions about the data Monsanto provided and that you

have reviewed to support the request for the 5% refuge in corn, and your

plans for the monitoring of insect resistance, monitoring plans, compliance, `etc. In particular I think it is important that you remind

CFIA of the differences in insect populations, overwintering, longevity,

etc. An example of the kind of discussion you may anticipate is provided below.

Overall, the selection for Bt resistance and the resistance risk in lepidopteran corn pests is significantly lower in Canada than US because:

- * most of these pest species cannot overwinter in Canada
- * these species generally go through fewer generations on

corn

each year in Canada than the US, and

* pest populations are typically smaller in Canada than the US

largely because of the first two factors.

In Canada, particularly because of overwintering temperatures,

the focus for IRM is on European corn borer, while southwestern corn borer, corn earworm and fall armyworm also must be considered in the US.

Of all the corn pest Lepidoptera, the level of control provided by both

proteins in MON 89034 is by far the highest for European corn borer (exceeding a "high dose" in both cases), and therefore the amount of refuge required for this pest is least. This means that the selection

of 5% refuge is highly conservative for Canada.

Russ

This e-mail message may contain privileged and/or confidential



Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314)-694-3143

800 NORTH LINOSERGH BLVD St. Louis, Missouri 63i67 http://www.monsento.com

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject:

Response to questions from EPA for insect-protected corn MON 89034 and MON

89034 × MON 88017 and supplemental information for MRIDs 46951302,

46951303, 46951402, and 46951403

EPA Petition Numbers 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly:

This letter is in response to the Agency's request from April 23, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn products MON 89034 and MON 89034 × MON 88017.

Responses to the Agency's questions are included in volume 2 of this submission. Supplemental information requested by the Agency for MRIDs 46951302, 46951303, 46951402, and 46951403 is provided in volumes 3-6. This submission includes documents that have been classified as 'A'- non-confidential documents that can be released to the public, or 'B' - data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers. A pdf file of documents classified as 'A' is included with this letter. Volumes 3 - 6 contain Standard Operating Procedures used in studies that we're submitted in support of the registration. Monsanto considers this information to be of a compositive nature because the methods described are components of an overall process established after years, of refinement to most efficiently and effectively generate data on products for regulatory and discovery work.

Volume	Document	Category	Hard copy	pdf. file for E-docket
N/A	Cover Letter	A	\	√
1	Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 4695 1400 and 4695 1300)	А	\checkmark	√
2	Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	A	√	V
3	Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"	В	\checkmark	
4	Supplemental Information for MRID No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"	В	√	
5	Supplemental Information for MRID No. 46951303 "Assessment of the Cryl A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"	В	√	
6	Supplemental Information for MRID No. 46951403 "Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"	В	√	

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto

Monsanto Regulatory Files

128



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Registration of Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA File 524-LTA and 524-LTL)

TRANSMITTAL DATE

May 11, 2007

MONSANTO REFERENCE No.

06-CR-172-3





Monsanto Company 06-CR-172E-3 Page 1 of 3

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1.	Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)	4			
	MRID Number				
Volume 2.	Responses to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)				
	MRID Number				
Volume 3.	Supplemental Information for MRID No. 46951302 "Confirmation of Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analys				
	MRID Number				
Volume 4.	Supplemental Information for MRID No. 46951402 "Amended Report MSL-20072: Molecular Analysis of Corn MON 89034"	for			
	MRID Number	> > > 3 > 2 > 5 > 2 > 5 > 5			
Volume 5.	Supplemental Information for MRID No. 46951303 "Assessment of the Cry1A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Corn MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"	33333 e ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	MRID Number	* 3			

Volume 6. Supplemental Information for MRID No. 46951403 "Assessment of the Cry1 A.105 and Cry2 Ab2 Protein Levels in Tissues of Insect-protected Corn MON 89034 Produced in 2005 U.S. Field Trials"

MRID Number		

Company Official:

When M. Bjolawore May 11, 2007

Natalia N Bogdanova, D.V.M. Regulatory Affairs Manager

(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Director, Regulatory Affairs

(202) 383-2866

Date



VOLUME 1

Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

AUTHOR

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

SUBMISSION DATE

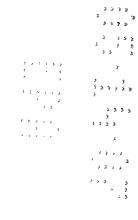
May 9, 2007

SUBMITTING REGISTRANT

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005

MONSANTO REFERENCE No.

06-CR-172-3





Monsanto Company 06-CR-172-3 Page 1 of 9

VOLUME 1

TABLE OF CONTENTS

Table of Contents	2
Administrative Materials	3
Application for Registration (Form 8570-1)	4
· · · · · · · · · · · · · · · · · · ·	
Certification with Respect to Citation of Data (Form 8570-34)	
Data Matrix (Form 8570-35)	e



ADMINISTRATIVE MATERIALS

Application to Register (Form 8570-1)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)



Monsanto Company 06-CR-172-3 Page 3 of 9

Please read instructions on re	verse before completin	g form.	Form A	pproved. OME	B No. 2	070-0060. /	Approval Ex	pires 2-28-95
& EPA	Environme r Was	United States Ital Protec thington, DC 2	tion Agenc	y		Registra Amend Other		OPP Identifier Number
	Applica	tion for Po	esticide – S	Section I				
t. Company/Product Number File Symbol 524-	t. Company/Product Number 2. EPA Product Manager 3. Proposed Classification File Symbol 524-LTL and 524-LTA Sheryl Reilly					ed Classification		
Company/Product (Name) MON 89034 and MON			DM #			e Restricted		
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 1300 I (Eye) Street, N.W., Suite 450 East Washington, DC 20005 Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name					
		Secti	ion – II	<u>,</u>				
Amendment – Explain Resubmission in responsation – Explain be Explanation: Use additional page(s) Submission of supplemental into facilitate review of studies supplemental supplemen	nse to Agency letter da elow. if necessary. (For Sec formation for MRI	ction I and Section Ds 46951300), 46951302, 4		er dated oplicatio lain bel	ow. 400, 4695	1402, and	d 46951403,
		Secti	on – III					
Material This Product Will Be Pac	kaged In:	OEC (I	<u> </u>		••••••		<u>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</u>	
		No. per	Water Soluble Portion Yes No If "Yes" Package wgt.	No. per Container		2. Type of C Meta Plass Glas Pape Othe	ll tic s er	
Location of Net Contents Information Label		4. Size(s) Retail	l Container		5. Loc	(Specify) ation of Lab in Label in Labeling a		
6. Manner in Which Label is Affixed to F	roduct	Lithograph Paper glue Stenciled	ed	Other			* 2 3 > 2 3 * 2 3	\$
Section – IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process his application.)								
1. Contact Point (Complete items direct Name Russell P. Schr	neider	Title I	o be contacted, if Director, Regu					nclude Area Code) 3-2866
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete, I acknowledge that any knowingly fatse or misleading statement may be punishable by fine or imprisonment or both under applicable law. Certification 6. Date Application Received Stamped)								
2. Signature Washes Washer Typed Name		5. Date	Regulatory A	ffairs Mana	ager		. : 3	3 3 3 3
Natalia N. Bogdanova	Tel. (314) 694-31		May 9, 2007					
EPA Form 8570-1 (Rev. 3-94)	Previous editions are	obsolete.	White - EPA	Fife Copy (o	riginal)	Yellow	- Applicant	Сору

(135)

Monsanto Company 06-CR-172-3 Page 4 of 9

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data						
Applicant's/Registrant's Name, Address, and Telephone Number:	···	EPA Registration Number / File Symbol:				
Monsanto Company, 1300 I (Eye) Street, N.W., Washington, D.	OC 2005 (202) 383-2866	524-LTL and 524-LTA				
Active Ingredient(s) and/or representative test compound(s): B.t. Cry1/		Date:				
and the genetic material (vectors ZMIR245 and ZMIR39) necessary for 89034 and MON 88017.	or their production in MON	May 9, 2007				
General Use Pattern(s) (list all those claimed for this product using 40 (CFR Part 158:	Product Name:				
Terrestrial field crop		MON 89034 and				
		MON 89034 x MON 88017				
NOTE: If your product is a t00% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption						
I am responding to a Data-Calt-in Notice, and have included w should be used for this purpose).	ith this form a list of companies	sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DA	TA SUPPORT (Check o	one method only)				
I am using the cite-all method of support, and have included we this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective me	selective method of support (or cite-all option under ethod), and have included with this form a of data requirements (the Data Matrix form must be				
Section II: GEI	NERAL OFFER TO PA	ıY				
[Required if using the cite-all method or when using the cite-al		· · · · · · · · · · · · · · · · · · ·				
I hereby offer and agree to pay compensation, to other person	s, with regard to the approval of	f this application, to the extent required by FIFRA.				
	: CERTIFICATION					
I certify that this application for registration, this form for reregistration, or this Oata-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.						
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) bamake original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commense negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.						
ি certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I বুলুknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Date	Typed or Printed Name and Title				
Water W. Bylaciena	May 9, 2007	Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager				

Page 5 of 9 (134)

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: May 9, 2007 Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005			EPA Reg. No./File Symbol: 524-LTA and 524-LTL Page to		
			Product: MON 89034 and MON 89034 x MON 88017		
Ingredient Bacillus thuring 89034 and MON 88017	giensis Cry1A.105, Cry2Ab2, and Cry3Bb1 and the	he genetic materia	al necessary for its production (vect	ors ZMIR245 and ZN	MIR39) in MON
Guideline Reference Number	Guideline Study Name	MRID Number Submitter		Status	Note
	Volume I. Administrative Materials for Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
	Volume 2. Response to EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect- protected Com MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission
885.1100	Volume 3. Supplemental Information for MRID No. 46951302 "Confirmation of the Integrity of Corn MON 89034 x MON 88017 by Southern Blot Analysis"		Monsanto Company	own	This Submission
885.1100	Volume 4. Supplemental Information for MRtD No. 46951402 "Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034"		Monsanto Company	OWN	This Submission
	L. M. Byllactoria		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date May 9, 2007	

EPA Form 8570-35*(9-97)*Electronic and Paper versions available, Submit only Paper version.

Agency Internal Use Copy



Monsanto Company 06-CR-172-3

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

——————————————————————————————————————	E	ATA MATRIX		·		
Date: May 9, 2007 Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005 Ingredient Bacillus thurringieusis Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material ne			Product: MON 89034 and MON 89034 x MON 88017 I necessary for its production (vectors ZMIR245 and ZMIR39) in MON			
885.1100	Volume 5. Supplemental Information for MRID No. 46951303 "Assessment of the Cry! A.105, Cry2Ab2, Cry3Bb1, and CP4 EPSPS Protein Levels in Selected Tissues of Insect-protected Com MON 89034 x MON 88017 Produced in 2005 U.S. Field Trials"		Monsanto Company	own	This Submission	
885.1100	Volume 6. Supplemental Information for MRID No. 46951403 "Assessment of the Cryl A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-protected Com MON 89034 Produced in 2005 U.S. Field Trials"		Monsanto Company	. OWN	This Submission	
10 and 10	**************************************					
	2010 and Parity Services available Submit only Bance ye		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date May 9, 2007	•	

EPA Form 857()-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency.

40 f M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX EPA Reg. No./File Symbol: 524-LTA and 524-LTL Page 1 of 2 Date: June 22, 2005 Applicant's/Registrant's Name & Address: Monsanto Company, 1300 I (Eye) Street, N.W., Suite 450 East, Washington, D.C. 20005 Product: MON 89034 and MON 89034 x MON 88017 Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 and the genetic material necessary for their production (vectors ZMIR245 and ZMIR39) in Ingredient MON 89034 and MON 88017 Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Monsanto Company OWN This Submission OWN This Submission Monsanto Company OWN This Submission Monsanto Company OWN This Submission Monsanto Company fil w. Bylancon Name and Title Date Signature Natalia N. Bogdanova, D.V.M. May 9, 2007 Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

	DATA MATRIX			
Date: May 9, 2007	EPA Reg. No./File Symbol: :	Page 2 of 2		
Applicant's/Registrant's Name & Address: Monsanto Company, 1300 1 (Eye) Street, N.W., Suite 450 East, Was	Product: MON 89034 and MON 89034 x MON 88017			
Ingredient Bacillus thuringiensis Cry1A.105, Cry2Ab2, and Cry3E MON 89034 and MON 88017	3b1 and the genetic material ne	essary for their production (ve	ectors ZMIR245 and ZM	IR39) in
Guideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
		Monsanto Company Monsanto Company	OWN	This Submission
Signature Made Myclaccone	No.	me and Title talia N. Bogdanova, D.V.M.	Date May 9, 2007	
	Re	gulatory Affairs Manager	,	





DEC 1 9 2007

OPP Decision Numbers:

D-371189

D-371190

Yong Gao Regulatory Affairs Manager Monsanto Company 1300 I Street, NW Suite 450 East Washington, DC 20005

Dear Dr. Gao:

Subject: MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and

MON89034 (Cry1A.105, and Cry2Ab2) Corn EPA Petition Numbers: 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL Application Date: September 29, 2006 EPA Receipt Date: September 29, 2006

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008.

Our review of your public interest document is ongoing. Provided that we are able to determine the registration of these products would be in the public interest, that you make the following changes to your proposed insect resistance management (IRM) refuges, and that you drop the proposed popcorn use, the Agency will be able to continue processing your applications.

If you choose not to modify the IRM refuge proposals and drop the popcorn use, the applications will be deemed incomplete. Within seventy-five (75) days, please indicate whether you will modify the IRM refuges and drop the popcorn use, and submit in writing a commitment to perform the required data listed below.

The Agency is requesting the following revisions to your proposed IRM refuges. Please consult the enclosed data evaluation records for detailed information.

CONCURRENCES							
SYMBOL ▶ 7511(7511P 7511Pa	nsuf.					
SURNAME Mondal	Reynolds Sprull	Rulf					
COLDITO TEAD	12/18/07 12/18/07	12/19/67		_ (141)			
EDA Form 1220 14 (1/90)	P	rinted on Recycled Paner	OFFIC	IAI EILE CORV			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 1 9 2007

OPP Decision Numbers:

D-37t189

D-371190

Yong Gao Regulatory Affairs Manager Monsanto Company 1300 I Street, NW Suite 450 East Washington, DC 20005

Dear Dr. Gao:

Subject: MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and

MON89034 (Cry1A.105, and Cry2Ab2) Corn EPA Petition Numbers: 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL Application Date: September 29, 2006 EPA Receipt Date: September 29, 2006

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008.

Our review of your public interest document is ongoing. Provided that we are able to determine the registration of these products would be in the public interest, that you make the following changes to your proposed insect resistance management (IRM) refuges, and that you drop the proposed popcorn use, the Agency will be able to continue processing your applications.

If you choose not to modify the IRM refuge proposals and drop the popcorn use, the applications will be deemed incomplete. Within seventy-five (75) days, please indicate whether you will modify the IRM refuges and drop the popcorn use, and submit in writing a commitment to perform the required data listed below.

The Agency is requesting the following revisions to your proposed IRM refuges. Please consult the enclosed data evaluation records for detailed information.

REVISED IRM REFUGES

MON 89034 field corn uses in the corn belt including the separate refuge for 89034 x 88017.

- (1) Pyramids can reduce the need for large refuges. Monsanto has proposed that a 5% structured refuge, rather than the current 20% structured refuge, be used with the field corn uses of MON 89034. However, Monsanto's data and modeling <u>do not</u> support a 5% structured refuge for MON 89034 for field corn uses in the Corn Belt. A 20% structured refuge requirement for field corn uses of MON 89034 in the Corn Belt can be supported at the present time.
- (2) <u>MON 89034 fleld corn use in cotton-growing areas.</u> A 20% non-Bt corn refuge for MON 89034 in the southern cotton-growing areas would be sufficient to manage the risk of resistance evolution to Bt corn and Bt cotton products <u>assuming there is no cross-resistance</u>. Refer to sections (3) and (4) below.

The following data deficiencies must be addressed post-registration to support a conditional registration with the above mentioned revised 20% non-Bt IRM refuges and no popcorn use sites.

DATA REQUIRED POST-REGISTRATION WITH REVISED IRM REFUGES

- (1) For event MON 89034 corn and event MON 89034 x MON 88017 corn, an independent lab validation of the analytical method for the detection of Cry2Ab2 and/or Cry1A.105 is needed.
- (2) Freshwater aquatic invertebrates for MON 89034 (MRID 469514-17)
 The Daphnia magna study is unacceptable because the 48 hour test duration is not sufficient to show mortality for Bt toxins. It takes more than 48 hours for the target pests to succumb to the Cry proteins therefore 48 hours is also too short to show mortality to Daphnia. A 21 day daphnia study, as outlined in the OPPTS Microbial Test Guidelines, needs to be performed. The study may be submitted as a condition of registration.
- (3) Monsanto did not address the likelihood of cross-resistance of Cry1A.105, Cry1Ac, Cry1Fa, proteins already in existing Bt corn and Bt cotton products, and what impact such cross-resistance would have on the durability of MON 89034. Monsanto must provide additional information on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (preferably including binding site models and use of resistant colonies) for the target pests and determine how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.
- (4) Monsanto did not sufficiently address the cross-resistance of Cry1A.105, Cry1Fa, and Cry1Ac in the cotton-growing landscape and how cross-resistance may impact the durability of MON 89034. Should cross-resistance be of concern then the durability of

MON 89034 in the southern cotton-growing areas might be compromised. Monsanto needs to address this issue in subsequent simulation modeling.

- (5) Monsanto is reminded that to support the sweet corn use site, a grower guide must be distributed to all customers using seed containing the plan-incorporated protectant that will include instructions and recommendations regarding product use, insect resistance management and integrated pest management. The following information regarding commercial productions must be included in the Grower guide:
 - Crop destruction must occur no later than 30 days following harvest, but preferably within 14 days.
 - The allowed crop destruction methods are rotary mowing, discing, or plow-down. Crop-destruction methods should destroy any surviving resistant insects.

If Monsanto chooses to register their products with a 5% structured refuge the following additional data are required.

DATA REQUIRED TO SUPPORT MON 89034 FIELD CORN USES IN THE CORN BELT WITH A 5% STRUCTURED REFUGE:

Monsanto must address the uncertainties in the dose determination for ECB, SWCB, CEW, FAW (SS and RS mortality), cross-resistance likelihood of Cry1A.105, Cry1Ac, and Cry1Fa and its impact on the durability of MON 89034, and limitations of the simulation modeling. Please also refer to the enclosed review for a full discussion of BPPD's analysis of the IRM plan for MON 89034.

- a) <u>Dose determination</u>. Monsanto relies on the Roush (1998) model to support the need for a 5% structured refuge rather than a 20% structured refuge in the Corn Belt. Roush's model (1998; Figure 2) indicates that a 5% structured refuge is equal to or greater than a 20% structured refuge for a highly effective, high dose single-gene product when a two-gene product (MON 89034 in this case) achieves at least 95% control of susceptible homozygotes <u>and</u> 70% control of heterozygotes assuming there is no cross-resistance. The dose information provided by Monsanto is not sufficient to demonstrate that each protein will kill 95% of the homozygous susceptible insects and 70% of the heterozygotes. BPPD recommends that Monsanto further investigate whether MON 89034 consistently has high mortality of susceptible homozygotes (>95%) and whether the heterozygote mortality is at least 70% for MON 89034 against the target pests (for the Corn Belt ECB and SWCB). The 1998 SAP suggested several ways to estimate mortality for less susceptible larvae (i.e. heterozygotes) (EPA 1998). These techniques included testing larger, later instar larvae that may be less susceptible.
- b) Cross Resistance. Additional information is needed on cross-resistance of Cry1A.105 and Cry1Fa and Cry1Ac (including binding site models and use of resistant colonies) for the target pests and a determination of how such cross-resistance may impact the durability of MON 89034. The Cry1A.105 protein is a chimeric protein consisting of Domains I and II and the C-terminus of Cry1Ac and Domain III of Cry1Fa. It



is important to address not only the likelihood of cross-resistance potential of Cry1A.105 and Cry1Ab and, similarly, Cry1A.105 and Cry2Ab2 (which was done by Monsanto), but also that of Cry1A.105 and Cry1Ac and Cry1Fa.

c) <u>Modeling</u>. Additional species-specific (e.g, ECB and SWCB for the Corn Belt), spatially-explicit, landscape modeling is needed to explore the durability of MON 89034 versus single-protein Bt corn products. Modeling should consider the impact of other Bt proteins in the landscape that may confer some cross-resistance (to Cry1A.105, in particular) and how such cross-resistance would impact the durability of MON 89034 in the Corn Belt (i.e., the use of simulation modeling). This is analogous to the species-specific simulation modeling that EPA required Monsanto do to support the use of natural refuge (instead of a structured refuge) for management of *H. virescens* and *H. zea* to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II cotton.

If you do not modify your refuge proposals as described above, the application will be deemed deficient.

Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for responding and subject to a new registration service fee.

Based on the content and timing of your response, the PRIA date for these applications may need to be renegotiated. Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,

Sheryl Reilly, Chief

Microbial Pesticides Branch Biopesticides and Pollution

Prevention Division (7511P)



To OPP BPPD MPB

CC

Subject Fw: Monsanto Corn Variety Genetically Engineered for Insect-Resistance derived from Transformation Event designated as MON 89034 - The USDA Animal and Plant Health Inspection Service has announced the receipt of a Monsanto petition seeking a determination of nonregulated status for the variety - APHIS is seeking public comment " ... on whether this genetically engineered corn is or could be a plant pest ..."

Monsanto Corn Variety Genetically Engineered for Insect-Resistance derived from Transformation Event designated as MON 89034 - The USDA Animal and Plant Health Inspection Service has announced the receipt of a Monsanto petition seeking a determination of nonregulated status for the variety - APHIS is seeking public comment " ... on whether this genetically engineered corn is or could be a plant pest ..."

Document Title: The title of the December 13, 2007 USDA APHIS Federal Register Notice is: "Monsanto Company; Availability of Petition and Environmental Assessment for Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance"

Organization: USDA APHIS Biotechnology Regulatory Services

Source: December 13, 2007 USDA APHIS Federal Register Notice

Comments Due By: February 11, 2008

Web site: The December 13, 2007 APHIS Federal Register Notice is posted at http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/200 7/E7-24174.htm

The petition and the environmental assessment are posted at http://www.aphis.usda.gov/brs/aphisdocs/06_29801p.pdf and http://www.aphis.usda.gov/brs/aphisdocs/06 29801p_ea.pdf

Contact: Questions may be directed to Dr. Robyn Rose, USDA APHIS Biotechnology Regulatory Services in Riverdale, Maryland at 30 I 734 0489; e-mail: Robyn.I.Rose@APHIS.USDA.gov

Paper copies of the petition and environmental assessment are available from Cindy Eck at 301 734 0667; e-mail: Cvnthia.A.Eck@APHIS.USDA.gov

Prepared by: This message was distributed by Jack Cooper, who may be reached at e-mail: <u>jlc@fien.com</u> or 301-384-8287

This article (#3363) was distributed by e-mail on December 13, 2007 to those whose names are on the FIEN, LLC Subject Matter Distribution Lists for Biotechnology, Crop Protection, Grains, Risk Assessment and Communication



Zigfridas Vaituzis/DC/USEPA/US 11/26/2007 12:13 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc Mike Mendelsohn/DC/USEPA/US@EPA

bcc

Subject MON 89034 corn Section 3

Susanne:

The only environmental effects 'deficiency' for MON 89034 corn is below:

ii. Freshwater aquatic invertebrates (469514-17)

Conclusions/Recommendations: The Daphnia magna study is unacceptable because the 48 hour test duration is not sufficient to show mortality for Bt toxins. It takes more than 48 hours for the target pests to succumb to the Cry proteins therefore 48 hours is also too short to show mortality to Daphnia. A 21 day daphnia study, as outlined in the OPPTS Microbial Test Guidelines, needs to be performed. The study may be submitted as a condition of registration.

Susanne: you and Mike can decide when exactly this study needs to be submitted. One year seems reasonable to me.

The rest of the DERs and the BRAD chapter with the risk assessments is done. I only need to go over it again to make several clarifications and update risk conclusions, especially for the aquatic invertebrates. No more "deficiencies" are forthcoming.

[zig.v]



Please read instructions on r	everse before completing f	orm.	Form A	proved. OM	B No. 20	070-0060.	Approval Ex	pires 2-28-95
⊕ EPA	Environmenta	nited States al Protec ngton, DC 2	tion Agenc	у		Regist Amend Other	J	OPP Identifier Number
	Applicati	on for P	esticide – S	ection I		· · ·		
Company/Product Number File Symbol 524	-LTL and 524-LTA		2. EPA Product				3. Propose	d Classification
Company/Product (Name) MON 89034 and MO		 17	PM# S2 None Restricted					Restricted
5. Name and Address of Applicant (Incjude ZIP Code) Monsanto Company 1300 I (Eye) Street, N.W., Suite 450 East Washington, DC 20005 Check if this is a new address			6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name					
		Secti	on – II					
Notification - Explain Explanation: Use additional page(Submission of the Public Inter	onse to Agency letter dated below. s) it necessary. (For Sections test Document Suppor	on I and Secti		Final printed Agency lette "Me Too" Ap Other – Exp	er dated oplication lain belo	n. ow.	······································	MON 89034 x
MON 88017 (EPA File 524-L	TL and 524-LTA)							
	***************************************	Secti	on – III					
1. Material This Product Will Be Pa Child-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No It "Yes" No		Water Soluble Pa Yes No If "Yes" Package wgt.	ockaging No. per Container		Z. Type of (Met Plas Gta: Pap Oth	al stic ss er	
3. Location of Net Contents Informatio	4.	Size(s) Retail	Container		5. Loca	ition of Lat n Labet	et Directions accompanyir	
6. Manner in Which Label is Affixed to	Product	Lithograph	t	Other				
		Paper glue Stenciled	ed					
			on – IV			~		
Contact Point (Comptete items direct	tty below for identification (be contacted, if	necessary, to	process			
Name Russell P. Sch	·····	F -1-11.111	or Director, R	egulatory A	Affairs	,	(202) 383	-2866
I certify that the statements I have I acknowledge that any knowing!; both under applicable law.	e made on this form and at	nent m ay be p				e.	3 *	Date Application Received tamped)
2. Signature Windows By de	acora	3. Title	Regulatory A	ffairs Mana	ager			,
4. Typed Name Natalia N. Bogdanova	Tel. (314) 694-3143		November 12,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				\$ 1
EPA Form 8570-1 (Rev. 3-94	i) Previous editions are o	bsolete	White - FPA	File Copy (or	riginal)	Yellow	- Applicant	Copy

149



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W.

WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address

DO NOT SOILE THE COMPLETE OF THE AUGUSTS.	DV NX 3010 the Competed form to this address.						
Certification with	Respect to Citation of	f Data					
Applicant's/Registrant's Name, Address, and Telephone Number:	EPA Registration Number / File Symbol:						
Monsanto Company, 1300 I (Eye) Street, N.W., Washington, I	OC 2005 (202) 383-2866	524-LTL and 524-LTA					
Active Ingrediens(s) and/or representative test compound(s): Bt Cry1 Cry3Bb1 proteins and the genetic material (vectors ZMIR245 and ZM production in MON 89034 and MON 89034 x MON 88017		Date: (13.22) November 12, 2007					
General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158:	Product Name: , *****					
Terrestrial field crop		MON 89034 and					
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption		ed for all the same uses on your label, you do not					
I am responding to a Data-Call-in Notice, and have included with should be used for this purpose).							
Section I: METHOD OF DA	TA SUPPORT (Check of	one method only)					
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose). I am using the selective method of support (or cite-all option to the selective method), and have included with this form a completed list of data requirements (the Data Matrix form musused).							
Section II: GENERAL OFFER TO PAY							
[Required if using the cite-all method or when using the cite-all	Il option under the selective me	thod to satisfy one or more data requirements]					
I hereby offer and agree to pay compensation, to other person	is, with regard to the approval o	of this application, to the extent required by FIFRA.					
Section II	I: CERTIFICATION						
It certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section It, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.							
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.							
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.							
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.							
t certify that the statements t have made on this form and all knowingly false of misteading statement may be punishable by fin							
Signature	Date	Typed or Printed Name and Title					
November 12, 2007 Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager							

\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency,

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.				
		DATA MATRIX			
Date: November 12, 2007		EPA Reg. No./File Symbol: 524-LTL and 524-LTA Page t of t			
Applicant's/Registrant's Name &				· · · · · · · · · · · · · · · · · · ·	
	(Eye) Street, N.W., Suite 450 East, Washington,		Product: MON 89034 an		
Ingredjent <i>Bacillus thuringi</i> 88017	ensis Cry1A.105, Cry2Ab2, and Cry3Bb1 and the gen	etic material necess	sary for its production (vectors ZMIR24	.5 and ZMIR39) in MON	1 89034 and MON
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Volume 1. Administrative Materials for the Submission of the Public Interest Document Supporting Registration of Bacillus rhuringiensis Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)		Monsanto Company	OWN	This Submission
	Volume 2. Public Interest Document Supporting Registration of Bacillus Illuringiensis Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 514-LTL and 524-LTA)		Monsanto Company	OWN	This Submission
	M. Bywlanna. 97) Electronic and Paper versions available «Submit college.		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date November 12, 2007	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

Agency Internal Use Copy



\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washin	glon, DC 20460. Do not send the form to this	· · · · · · · · · · · · · · · · · · ·			
		DATA MATRIX			
Date: June 22, 2005		EPA Reg. No./File Symbol:	TA Page 1 of 1		
Applicant's/Registrant's Nar					
	00 I (Eye) Street, N.W., Snite 450 East, V		Product: MON 89034 at		
Ingredient Bacillus the 89034 and MON 88017	uringiensis Cry1A.105, Cry2Ab2, and C	Cry3Bb1 and the genetic material ne	ecessary for its production (vecto	rs ZMIR245 and Z	MIR39) in MON
Guideline Reference Numbe	er Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanio Compatty Monsanto Company	OWN	This Submission This Submission
Signature Wash	L. Bylancon	1	Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date November 12, 20	
	***			.i	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.

Public File Copy



Please read instructions on re	everse before completing form.	Form Approved.	OMB No. 2070-0060. Ap	proval Expires 2-28-95	
SEPA	United Sta Environmental Prot Washington, D	ection Agency	Registrat Amendm Other	Number	
	Application for	Pesticide - Sectio			
1. Company/Product Number File Symbol 524	2. EPA Product Manage	2. EPA Product Manager Sheryl Reilly 3. Proposed Classific			
Company/Product (Name) MON 89034 and MOI	N 89034 × MON 88017	PM#	PM# 92		
5. Name and Address of Applicant (In Monsanto Company 1300 I (Eye) Street, N.W., Su Washington, DC 20005 Check if this is a new address	product is similar or iden EPA Reg. No.	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(B)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name			
· <u> </u>	Se	ction – II			
Notification – Explain	onse to Agency letter dated below.	Agency "Me To Other -	rinted tabels in response to r letter dated o" Application. - Explain below.		
Explanation: Use additional page(s Submission of the Public Inter MON 88017 (EPA File 524-L	est Document Supporting Re IL and 524-LTA)	gistration of Insect-prote	ected Corn MON 890	34 and MON 89034 x	
		ction – III		7 3 3 3 3 3	
1. Material This Product Will Be Pa	Unit Packaging Yes	Water Soluble Packaging Yes No	Metal	123317 ntainer 2 23359 2 2 2 3 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	
* Certification must be submitted	If "Yes" No. per Unit Packaging wgt. Container	if "Yes" No. pe Package wgl. Conta		5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5 5	
3. Location of Net Contents Informatio	n 4. Size(s) R	elail Container	5. Location of Label	Directions companying product	
6. Manner in Which Label is Affixed to	Paper Stenc	glued iled	Diher		
Contact Point (Complete ilems direct		ction - IV	une to propose this continue	ion l	
Name Russell P. Sci	Title nneider S	Senior Director, Regulat	Telepho	one No. (Include Area Code) 202) 383-2866	
	Certificatio e made on this form and all atlachm r false or misleading stalement may	ents thereto are Irue, accurate		6. Date Application Received (Stamped)	
2. Signature	3. T	itle Regulatory Affairs I	Manager		
4. Typed Name Natalia N. Bogdanova	Tel. (314) 694-3143	ate November 12, 2007			
EPA Form 8570-1 (Rev. 3-9-	l) Previous editions are obsolete.	White - EPA File Co	py (original) Yellow - A	Applicant Copy	



&EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with F	Respect to Citation of	Data				
Applicant's/Registrant's Name, Address, and Telephone Number:		EPA Registration Number / File Symbol:				
Monsanto Company, 1300 I (Eye) Street, N.W., Washington, D	C 2005 (202) 383-2866	524-LTL and 524-LTA				
Active Ingredient(s) and/or representative test compound(s): Bt Cry1	A.105, Cry2Ab2 and	Date:				
Cry3Bb1 proteins and the genetic material (vectors ZMIR245 and ZM production in MON 89034 and MON 89034 x MON 88017	IR39) necessary for their	November 12, 2007				
General Use Pattern(s) (list alt those claimed for this product using 40 C	CFR Part 158:	Product Name:				
Terrestrial field crop		MON 89034 and				
}		MON 89034 x MON 88017				
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption						
I am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of companies	sent offers of compensation (the Data Matrix form				
Section I: METHOD OF DA	TA SUPPORT (Check of	one method only)				
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose). I am using the selective method of support (credits-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form this string the selective method).						
Section II: GEI	NERAL OFFER TO PA	Y 3 3 3 8 8				
(Required if using the cite-all method or when using the cite-all	option under the selective met	thod to satisfy one or more ដងនៃ requiremeគង្គៀ ៖្ខ				
t hereby offer and agree to pay compensation, to other person	s, with regard to the approval o	of this application, to the extent required by FiFRA.				
Section III: CERTIFICATION						
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option is given the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
I certify that for each exclusive use study cited in support of thi obtained the written permission of the original data submitter to cite tha		that I am the original data submitter or that I have				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fall to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.						
I certify that the statements I have made on this form and at knowlngly fatse of misleading statement may be punishable by fin						
Signature	Date	Typed or Printed Name and Title				
Mather A Bylana	November 12, 2007	Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager				
EPA Form 8570-34 (9-97) Flectronic and Paper Versions available						

⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.				
		DATA MATRIX			
Date: November 12, 2007		EPA Reg. No./File Symbo	d: 524-LTL and 524-LT	A Page t of I	
	(Eye) Street, N.W., Suite 450 East, Washington,		Product: MON 89034 ar		
Ingredient Bacillus tlurringi 88017	ensis Cry1A.105, Cry2Ab2, and Cry3Bbt and the gen	etic material necess	ary for its production (vectors ZMIR24	15 and ZMIR39) in MON	89034 and MON
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Volume I. Administrative Materials for the Submission of the Public Interest Document Supporting Registration of Bacillus thuringieusis Cryl A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Com MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)		Monsanto Company	OWN	This Submyssion
	Volume 2. Public Interest Document Supporting Registration of <i>Bacillus thuringieusis</i> Cryt A. 105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Com MON 89034 and MON 89034 x MON 88017 (EPA Files 514-LTL and 524-LTA)		Monsanto Company	OWN	This Submission
	A. P. Carren		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date November 12, 2007	
EPA Form 8570-35 (Q.)	97) Electronic and Paper versions available. Submit only	t.Paper version		Agency internal Use	Conv

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency internal Use Copy



06-CR-172

Page 5 of 6

SEPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date: June 22, 2005			EPA Reg. No./File Symbol:	524-LTL and 524-LT.	A Pagelofi
	& Address: (Eye) Street, N.W., Suite 450 East, Washington ngiensis Cry1A.105, Cry2Ab2, and Cry3Bb1 and		Product: MON 89034 ar		
Ingredient Bacillus thuri 89034 and MON 88017	igiensis CiylA.103, Ciy2A02, and Ciy3B01 and	d the generic material	necessary for its production (vecto	IS ZIVIIIX 245 and ZIV	III MON
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Submission
				a constant	
			Monsanto Company	OWN	This Submission
Signature Signature	Company of the second		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date November 12, 200)7

EPA Form 8570-35 (9-97) Electronic and Paper versions ovailable. Submit only Paper version,

Public File Copy



Monsanto Company

06-CR-172-5 🖔 🗸 🖔



VOLUME 1

Administrative Materials for the Submission of the Public Interest Document Supporting Registration of *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (EPA Files 524-LTL and 524-LTA)

AUTHOR

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

SUBMISSION DATE

November 12, 2007

SUBMITTING REGISTRANT

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005

MONSANTO REFERENCE No.

06-CR-172-5

157)

Monsanto Company 06-CR-172-5 Page 1 of 6

TABLE OF CONTENTS

2
3
4
5





Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143 MONSANTO COMPANY
800 NORTH LINOBERGH BLVD
ST. LOUIS, MISSOURI 63167
http://www.monsanto.com

November 12, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject: Public Interest Document Supporting Registration of Bacillus thuringiensis

Cry1A.105, Cry2Ab2 and Cry3Bb1 Proteins and the Genetic Material Necessary for Their Production in Insect-protected Corn MON 89034 and

MON 89034 x MON 88017 (EPA Files 5/4-LTL and 524-LTA)

Dear Dr. Reilly:

On September 28, 2006 Monsanto submitted an application to register *Bacillus thuringiensis* Cry1A.105, Cry2Ab2 and Cry3Bb1 proteins and the genetic material necessary for their production in insect-protected corn MON 89034 and MON 89034 x MON 88017 (EPA Files 5½4-LTL and 524-LTA). On October 17, 2007 the Agency suggested that Monsanto should provide a Public Interest Document that would outline benefits of the products. We do so with the belief that because no new data required for registration is being submitted, the current PRIA date will not be impacted.

This submission contains administrative materials and a Public Interest Document for MON 89034 and MON 89034 x MON 88017. These documents have been classified as "A" - non-confidential documents that can be released to the public.

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Notebol Papilicion

Sincerely,

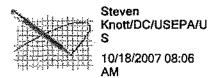
Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD Russ Schneider, Monsanto Monsanto Regulatory Archives

(159)

LIST OF SUBMITTED DOCUMENTS

Volume 1.	Suppo Cry3B Insect-	istrative Materials for the Submission of the rting Registration of <i>Bacillus thuringiensis</i> b1 Proteins and the Genetic Material Neces protected Corn MON 89034 and MON 89024-LTL and 524-LTA)	Cry1A.105, Cry2Ab2 and sary for Their Production in
	MRID	Number	
Volume 2.	Cry1A Neces	Interest Document Supporting Registration 105, Cry2Ab2 and Cry3Bb1 Proteins and t sary for Their Production in Insect-protected 89034 x MON 88017 (EPA Files 514-LTL	he Genetic Material I Corn MON 89034 and
	MRID	Number 47279701	
Company Of	ficial:	Natalia N Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143	November 12, 2007 Date
Company Na	me:	Monsanto Company	
Company Co	ntact:	Russell P. Schneider, Ph.D. Senior Director, Regulatory Affairs (202) 383-2866	



To Mike Mendelsohn/DC/USEPA/US@EPA

CC

Subject February Meeting

Mike,

We would like to publish the FR notice for the February meeting on November 14. Therefore, we'll need the key pieces of information from the profile sheet (title, abstract, areas of expertise necessary to address the charge) by about October 29.

Please let me know if there are any questions regarding the profile.

Thanks.

Steve

Steven M. Knott Executive Secretary FIFRA Scientific Advisory Panel 202-564-0103 knott.steven@epa.gov Sharlene Matten/DC/USEPA/US 10/18/2007 11:06 AM To Mike Mendelsohn/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

bα

Subject Re: Fw: February Meeting

I feel strongly that the science does not support Monsanto's proposal to reduce the 20% structured refuge to 5% structured refuge for the Corn Belt without additional data. At this time, a SAP is not necessary. We can justify the current structured refuge requirements for the Corn Belt. It is also likely that we can justify changing the 50% structured refuge to 20% structured refuge for Bt corn grown in cotton-growing areas without going to a SAP. If and when Monsanto can send in additional data and modeling to support the 5% structured refuge in the Corn Belt then we would likely to need a SAP—the change to the structured refuge requirements is significant and the transparency of an external peer review is warranted.

Sharlene

Sharlene R. Matten, Ph.D. Biologist USEPA/OSCP (7502M) 1200 Pennsylvania Ave., NW Washington D.C. 20460 202-564-0130

Mike Mendelsohn/DC/USEPA/US



Mike Mendelsohn/DC/USEPA /US 10/18/2007 10:03 AM

To Alan Reynolds/DC/USEPA/US@EPA, Sharlene Matten/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

CC

Subject Fw: February Meeting

Alan and Sharlene,

Any way we can make a final decision on whether we need an SAP at this time? Please advise. Thanks,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
http://www.epa.gov/pesticides/biopesticides
----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 10/18/2007 10:02 AM -----





Susanne Cerrelli/DC/USEPA/US 07/25/2007 0 t:26 PM

- To Sheryl Reilly/DC/USEPA/US@EPA
- Mike Mendelsohn/DC/USEPA/US@EPA, Rebecca Edelstein/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA, Sharlene
- bcc Keith Matthews/DC/USEPA/US@EPA; Chris Kaczmarek/DC/USEPA/US@EPA
- Subject Items forThursday July 26, 2007 Biotech Agenda- MON 89034

Sheryl-

After speaking with Mike M. today we identified the following proposed Agenda items:

- (1) Janet communicated the need for an analytical method to detect Cry1A.105 (DNA based or protein based). This had been discussed at earlier biotech meeting and with Rebecca and John. Our understanding is that this method is needed to support tolerance petition.
- a) We would like to explain that the Cry 2Ab2 and Cry 1A.105 are both on the MON 89034 insert. and the current registrations are specific for this MON 89034 vector in corn. The current available method would be adequate to detect the protein from these pending registrations. The proposed tolerance exemption is broad and will not be exclusive to corn, and we have no method for other crops.
- b) Can Janet please confirm that we need to require this method? If so can it be issued as a condition of registration?, Or do we need the method before we can register these products?
- c) This decision concerning the method impacts the SAP date and PRIA date.
- (2) Do we need to renegotiate the date based on this requirement? Other deficiencies were noted concerning sweet corn and pop-corn expression data.
- (3) Update concerning SAP plan for Mon 89034 IRM issues.

The date we currently have (December 12-14) will not work: (a) Alan and Sharlene have a conflict in schedules (b) the conference rooms are booked, so we'd have to book Hotel.

Steve Knotts conveyed that they try to avoid scheduling January and Feb SAPs because of snow/weather closings that can hit. Currently there is a Carbofuran meeting scheduled Early February.

Steve mentioned the option of combining this SAP with another one, because we expect this to be short SAP.

He needs at least 4 months notice as the FR needs to come out 90 days before meeting and materials need to be prepared.

We need to make a decision soon about whther we need meeting and when

(4) Head's up @ changes in FR Notices of receipts for PIPs with stacked proteins. The notice that was prepared for Cry1A 105 was modified after OGC input to add mention of potential change of use pattern and mention the prior registered Al that is contained with the new protein. This is a change in how we have handled this before. OGC (Keith Mathews and Chris Kaczmarek) need to be available for any discussion. OGC stated we need to inform the public.

- (a) When does underlying registration require additional notices?
- (b) Here is the notice that should publish any day now.



notice of receipt.pdf

(c) Here is Keith Mathews explanation (email) - for background information below.

Mike: I did do some digging and came up with actual written analysis on this topic. Granted this draft is from a few years ago, but, I'm ever more certain that my position on this topic has not changed over the years.



3c4-FR Question re Stack~4.bppd.wpd

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0208; FRL-8129-7]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products that contain new active ingredients not included in any currently registered products and/or that entail a changed use pattern pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Comments must be received on or before [insert date 30 days after date of publication in the Federal Register].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2007-0208, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2007-0208. EPA's policy is that all comments received will be included in the docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations gov or e-mail. The Federal regulations gov website is an "anonymous access"

	-		· · · · ·	CONCURRENC	,55	 	
SYMBOL 7	511P	75718	7511P.	75119		 1.0	
SURNAME >	Ceruli	mel	120100	Rulls			
DATE	126/07	6/28/27	62807	7/2/07		 7	(165)
			1				

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0208; FRL-8129-7]

Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products that contain new active ingredients not included in any currently registered products and/or that entail a changed use pattern pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Comments must be received on or before [insert date 30 days after date of publication in the Federal Register].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2007-0208, by one of the following methods:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the on-line instructions for submitting comments.
- Mail: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- Delivery: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2007-0208. EPA's policy is that all comments received will be included in the docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and



included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available in regulations.gov. To access the electronic docket, go to http:/ /www.regulations.gov, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov web site to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at http://www.regulations.gov, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8077; e-mail address: cerrelli.susanne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).



This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

- 1. Submitting CBI. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.
- 2. Tips for preparing your comments. When submitting comments, remember to:
- i. Identify the document by docket ID number and other identifying information (subject heading, Federal Register date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

(168)

II. Registration Applications

EPA received applications as follows to register pesticide products that contain active ingredients not included in any previously registered products and/or that entail a changed use pattern pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

Products Containing Active Ingredients not Included in any Previously Registered Products and/or Products for Which a Changed Use Pattern is Proposed

- 1. File Symbol: 524-LTL. Applicant: Monsanto Company, 800 N. Lindberg Blvd., St. Louis, MO 63167. Product name: MON 89034. Product type: Plant-Incorporated Protectant. Active ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) and Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3). Proposal classification/Use: None.
- 2. File Symbol: 524-LTA. Applicant: Monsanto Company, 800 N. Lindberg Blvd., St. Louis, MO 63167. Product name: MON 89034 x MON 88017. Product type: Plant-Incorporated Protectant. Active ingredients: Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3), Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (Vector ZMIR 245) in event MON 89034 corn (OECD Unique Identifier: MON-89034-3) and the previously registered active ingredient Bacillus thuringiensis Cry3Bb1 protein and the genetic material (Vector ZMIR 39) necessary for its production in event MON 88017 corn (OECD Unique Identifier: MON-88017-3). Proposal classification/Use: None.

List of Subjects

Environmental protection, Pesticides and pest.

Dated:

 $\label{lem:proposition} \textit{Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.}$

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 6560-50-S

ANAL YSIS

SUBJECT: Should EPA Publish Section 3(c)(4) Federal Register Notices Announcing Receipt of Applications for Registration of Stacked or Pyramided Plant-Incorporated Protectant Products that Contain Previously Registered or Announced Active Ingredients?

Background

- On 21 August 2002, BPPD received an application from Monsanto for a corn plant-incorporated protectant with Cry3Bb1 (rootworm new active ingredient) and Cry1Ab (registered as active against ECB). This is considered a stacked commercial registration of the two actives.¹
- EPA has already published a 3(c)(4) notice announcing an application tor a plant-incorporated protectant product containing Cry3Bb1 alone.
- UCS and Environmentat Detense have commented on the current Cry3Bbt CRWV docket that gene stacking raises potential environmental risks that have not previously been addressed by EPA.
- Monsanto stated the following in the 524-LUL application.

As the public has already had mutitiple opportunities to comment on the risks end benefits of the Cry1Ab and Cry3Bbt pant-incorporated protectants, the need for a public comment period on this application would appear to be unwarrented (sic.). Furthermore, it has not been Agency practice to publish a notice of receipt or open a public comment period tor applications to an register end-use product containing mutitiple active ingredlents (i.e., package mixtures).

Mike Mendelsohn informs us that Monsanto's last point is incorrect regarding EPA's practice for applications to register end-use products with multiple active ingredients. According to Mike, RD BPPD (Note: Both the viral replicase/Cry3A stacket product in pointines and the Boltgard II Cry1Ac/Cry3Ab2 stacked product in cotton were atteomical per 3(c)(4) because they contridued new active ingradients.) has previously, at least in some instances, published 3(c)(4) notices for applications to combine active ingredients registered-chemical-products. Also, Mike has indicated that it is EPA's practice when two applications to the same at, have come in at around the same time to also publish a second 3(c)(4) notice tor the later-in-time application. (Note: This practice has occurred when

2 companies are working together and submit their applications concurrently. Both 3(c)(4) notloes are combined or published together even though application submission dates do not always match.)

Relevant Statutory and Regulatory Provisions

- Section 3(c)(4) of FIFRA requires that EPA publish notice of "each application for registration of any pesticide it it contains any new active ingredient or it it would entail a changed use pattern."
- Section 10(b) of FIFRA provides that EPA shall not make public information that, in EPA's judgment, "contains or retates to trade secrets or commercial or timancial information obtained from a person and privileged or confidential".
- Interpreting FIFRA section 3(c)(4), section 152,102 requires that EPA publish in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient, or that proposes a new use for an active ingredient.
- 40 C.F.R. § 174.3 detines a PIP active ingrection as "a pesticidat substance that is intended to be produced and used in a living plant, or in the produce thereot, and the genetic material necessary for the production of such a pesticidal substance."
- Section 174.3 defines genefic material necessary for the production as "genetic materiat that encodes a substance or leads to the production of a substance; and regulatory regions."
- 40 C.F.R. § 152.3(p)(3) provides that "new use, when use with respect to a product containing a particular active ingedient, means: . . . (3) Any additional use pattern that would result in a significant increase in the levet of exposure, or a change in the route of exposure, to the active ingredient of man or other ornals me."
- Note that "new active ingredient" is not expressly defined by either FIFRA or in EPA's FIFRA regulations.

Discussion

The primary issues raised here are (1) whether Section 3(c)(4) requires that EPA publish a notice announcing receipt of a product in which active ingredients are stacked or pyramided - notwithstanding the registration status of the active higredients; (2) whether EPA is required to publish a 3(c)(4) notice if an active ingredient included in a stack or pyramid has previously been noticed, but not registered; and (3) whether EPA should consider plant-incorporated protectant registration applications as subject to FIFRA Section 10 CBI protection.

For purposes of this discussion, we are applying the 174.3 definition of the term "active ingredient," in the FIFRA section 3(c)(4) analysis. Also, EPA's practice when two applications for the same a.i. have come in at around the same time is also instructive. It is our current understanding that, in such cases, EPA publishes a second 3(c)(4) notice for the later-in-time application.

We believe that in many, if not most cases, EPA should publish a notice pursuant to Section 3(c)(4) to announce receipt of applications for stacked or pyramided products. First, Section 3(c)(4) requires publication of notice of an application for registration if the application concerns "any new active ingredient or if it would entail a changed use pattern," (Note: Active ingredients can have a more broad variance then described here. At this point, if the construct shot or otherwise used to transform the plant is the same; we have considered it the same active ingredient. These decisions have been made on a casd-by-case basis and may vary depending on the circumstances.) For plant incorporated protestante, the pertinent aspect of the regulatory definition of "active incredient" is "the genetic material necessary for the production of such posticidal substance," which is further defined as the "genetic material that encodes a substance or leads to the production of a substance; and regulatory regions." Thus, DNA code that leads to the production of a particular posticidal protein, but that is not identical to similar code leading to the production of such posticidal protein would constitute a new active ingredient. More importantly, however, changes in promotors or regulatory regions also could result in a "new" active ingredient. See, e.g., Regulations Under FIFRA for Plant-Incorporated Protectants, 66 Fed. Reg. 37772, 37788/1-(July 19, 2001) ("[A] modification to a regulatory region could result in a new formulation, a new use, or a new active ingredient."). As-EPA-explained in the Plant-Incorporated Protectants rule. "Felvaluations to assess the potential for risks associated with such changes [i.e., regulatory region afterations) typically occur in a new registration action or an action amending an existing registration." This explanation is consistent with an interpretation of the Part 174 definition of "active incredient" as encompassing the concept that changes in, inter-alia, (i) DNA-code regions; (ii) promoters; or (iii) regulatory regions likely will-constitute a "new" active ingredient. Moreover, BPPD's position is that a different incertion point for a DNA construct also could constitute a new active ingredient.

Second, stacked or pyramided products are also likely to result in "significant increase[s] in the level of exposure" to the active ingredient. For example, with respect to the application discussed in Background above, the stacked active ingredients, which previously would have been applied by growers seeking to destroy, repet, or mitigate separately ECB and CRW - but not bolh at the same time - now will be available to growers seeking to destroy, repet, or mitigate either or both pests. This appears, as a matter of fact, almost certain to result in significant increases in the level of exposure to each active ingredient.

Third, EPA should consider that failing to publish a Section 3(c)(4) notice for an

application for a stacked or pyramided product could result in negative implications for EPA making a NEPA functional equivalency argument should NEPA claims be raised in a litigation on such a registration as there will be no public participation phase during the decision making process.

With respect to the question of whether EPA is required to publish a 3(c)(4) notice if an active ingredient included in a stack or pyramid has previously been noticed, but not registered, there is an additional reason for publishing another 3(c)(4) notice for the pyramided or stacked product. It is our understanding that EPA has published notices on these second-in-time applications in the past under such circumstances. If this is indeed the case, then EPA has essentially inferpreted a second-in-time application of a not-yet-registered active ingredient as a "new active ingredient" for purposes of section 3(c)(4). Therefore, under its own interpretation, EPA should publish a notice for the second-in-time pyramided/stacked PIP. BPPD: [Is this 'publish the second in time' practice uniform? If not, it might represent a voluntary practice and not an interpretation of what we are required to do] (Note: My understanding is that the practice is uniform, but I am not sure.)

Regarding whether confidential business information (CBI) concerns implinge on this discussion, we note that Section 10(b) of FIFRA provides that EPA shall not make public information that, in EPA's judgment, "contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or contidential." To our knowledge, OPP has not made a determination that an application for registration of a product containing an active ingredient present in previously registered products constitutes information that should be afforded confidential treatment. Moreover, EPA makes clear af section 174,9 that the Agency expects CBI claims for plant-incorporated protectant products to be minimized to the extent possible. Where an applicant wishes to request CBI treatment for a submission related to a plantincorporated protectant, that request must accompany the submission to EPA. Failure to include a request for CBI treatment at the time of submission constitutes a waiver of such treatment for all information submitted at that time. 40 C.F.R. § 174.9(a). Thus, to the extent an applicant for registration of a stacked or pyramided product has not requested CBI treatment for specific data or information concurrent with the submission of the application, such applicant has waived the opportunity for confidential treatment of data or information associated with such application.

Conclusion

In sum, based on EPA's stalutory authority, the specific regulations applicable to plant-incorporated protectants, and EPA's past practices, it appears that it would likely be most appropriate for EPA to publish a 3(c)(4) notice announcing receipt of a product in which plant-incorporated protectant active ingredients are stacked or pyramided -notwithstanding the registration slatus of the active ingredients or whether both active ingredients have been previously the subject of a 3(c)(4) notice for another pesticide product. In mest some cases it is likely that the stacked or pyramided product will contain a "new active Ingredient" under the new PIP rule. In addition, it is likely that such a product will "entail a changed use pattern" as that is detined in the Part 152

regulations. Moreover, in the situation where one or both active ingredients have been "noticed" under 3(c)(4) but not yet registered, based on EPA's past practice, it would appear that the Agency has interpreted a later-in-time application as containing a "new active ingredient" until such "noticed"

"Sjacked" because the two active ingredients act to destroy, repel, or mitigate different pests. A "pyramided" product contains active ingredients that act to destroy, repel, or mitigale the same pest.



Sharlene Matten/DC/USEPA/US 07/23/2007 02:50 PM To Alan Reynolds/DC/USEPA/US@EPA, Susanne Cerrelli/DC/USEPA/US@EPA

cc

bcc

Subject Attachments: MON 89034: IRM and Benefits studies plus comments on Public Interest Finding, sweet com and popcorn uses

Forgot the attachment. SRM

Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514

----Forwarded by Sharlene Matter/DC/USEPA/US on 07/23/2007 02:51PM -----

To: Susanne Cerrelli/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA

From: Sharlene Matten/DC/USEPA/US

Date: 07/23/2007 02:46PM

Subject: MON 89034: IRM and Benefits studies plus comments on Public Interest Finding,

sweet corn and popcorn uses

Susanne -- I extracted, from an earlier table you sent to me, all of the IRM and efficacy and insect spectrum studies that Alan and I are reviewing. We are doing the IRM Plan review together. I am doing all of the efficacy and insect spectrum studies. I did not have all of the Submission information in all cases.

I do not have any document that would be used to make a Public Interest Finding should there be a conditional registrationunder 3(c)7(C). I would not assume that registration of MON 89034 will be an unconditional 3(c)5 registration; therefore, we need to make a Public Interest Finding and have a document from Monsanto that gives us the appropriate information to make such a finding.

In addition, we do not have sufficient information (expression and activity) to complete an IRM assessment for sweet corn. We have no information on popcorn. My recommendation is that Monsanto withdrawal both the sweet corn and popcorn uses until such information can be generated and submitted to EPA to support these uses

Sharlene
 Sharlene R. Matten, Ph.D.
 Biologist
 USEPA/OPP/BPPD (7511P)
 1200 Pennsylvania Ave., NW
 Washington D.C. 20460
 703-605-0514



IRM and 8enefit studies.doc

Mon 89034 + X External -> Morganto

Ned Letter Validated detection

(175)

IRM and Benefit Studies for MON 89034

SRM	Tonic Studie	s for MON 8	· I	Comp. D. H.C. and Y. W. and T. at
SKM		46951304	В	Camp, R.; Uffman, J.; Vaughan, T.; et.
				al. (2006) An Evaluation of the Insect
				Bioefficacy of Combined Trait Products
				Produced Through Conventional
				Breeding: MON 89034 x NK603 and
		ļ		MON 89034 x MON 88017. Project
	<u> </u>			Number: 06/01/50/02, MSL/20336.
				Unpublished study prepared by
				Monsanto Company. 24 p.
SRM		46951413	В	Macrae, T.; Brown, C.; Levine, S.
				(2006) Spectrum of Insecticidal Activity
				of Bacillus thuringiensis Cry1A.105
		-		Protein. Project Number: 04/01/39/27,
				MSL/20230. Unpublished study
				prepared by Monsanto Company. 18 p.
SRM		46951414	В	Macrae, T.; Brown, C.; Levine, S.
				(2006) Spectrum of Insecticidal Activity
			İ	of Bacillus thuringensis Cry2Ab2
			Į	Protein. Project Number: 05/01/62/07,
				MSL/20229. Unpublished study
				prepared by Monsanto Company. 17 p.
SRM	S799762	46951415	В	Headrick, J.; Heredia, O.; Oyediran, I.;
SIGN	3199102	40931713	1 2	et. al. (2006) Assessment of the
				Efficacy of Lepidopteran-protected
į	į			Corn MON 89034 and MON 89597
				Against Major Insect Pest in the United
İ				States, Puerto Rico and Argentina
				During 2003-2004 Seasons. Project
ļ				Number: 05/RA/39/05. Unpublished
				study prepared by Monsanto Company.
	OMAA			18 p.
AR and	S799762	46951430	В	Head, G. (2006) Insect Resistance
SRM				Management Plan for Second
Ì	1	,		Generation Lepidopteran-Protected
				Corn, MON 89034. Project Number:
				06/RA/39/06. Unpublished study
			············	prepared by Monsanto Company. 98 p.
SRM		47079400	A (has	Monsanto Co. (2007) Submission of
			CSF	Efficacy Data in Support of the
			classified	Application for Registration of MON
-	İ		C)	89034 X 88017. Transmittal of 2



				Studies.
SRM	S799763	469513-	В	Head, G. (2006) Insect Resistance
		06		Management Plan for the Combined
				Trait Product MON 89034 X MON
				88017. Unpublished study prepared by
				Monsanto Company. 18p.
SRM		470794-	В	Headrick et al. (2006). Assessment of
		03	İ	the Efficacy of Insect-protected Corn
			ļ	MON 89034, MON 89034 X NK 603,
				and MON 89034 X MON 88017
				Against Major Pests in the Field Trails
				Conducted in the U.S. During 2005

.





Sharlene Matten/DC/USEPA/US 07/16/2007 04:06 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

CC Alan Reynolds/DC/USEPA/US@EPA

bcc

Subject Found a bit of bridging for sweet corn - sweet corn still deficient

MRID 470794-02, p. 12, has a paragraph comparing the expression levels of the Cry1A.105 and Cry2Ab2 proteins in leaf tissues collected from MON 89034 sweet corn growin in Hawaii during 2007 to the levels previously reported for MON 89034 field corn grown in the Mainland U.S. (MRID 469514-03). The field corn data is represented for several locations while the sweet corn data is represented by one location in Hawaii (a suitable commercial source?). Additional sweet corn expression data and efficacy data are needed to support the sweet corn use.

There is no popcorn data of any kind. Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514



Sharlene Matten/DC/USEPA/US 07/16/2007 02:18 PM To Mike Mendelsohn/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA, Janet

CC

bcc

Subject Information to consider Re: MON 89034 & Possible SAP Conversation with Steve Knott

Sheryl and Mike:

Alan and I are scheduled to Lead a Symposium that we co-organized at the Annaul Entomological Society of America meeting December 9-12, 2007 at the Town and Country Resort and Convention Center in San Diego, California.

One of us needs to make sure we are in San Diego as we co-organized this symposium on Bt crop resistance monitoring (10 speakers - we are in one of the Big Section Symposia so we should get a lot of folks attending). We do not know yet when this symposium will be scheduled during that week. We can make a plea with the Organizing Chair for our Symposium to placed Dec 9, 10, or 11 as I have been in contact with him several times over the past few months.

However, for planning purposes, we are safe with Dec. 13 and 14th. Please advise.

Thank you.

Sharlene

Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514

----Forwarded by Sharlene Matten/DC/USEPA/US on 07/16/2007 02:14PM ----

To: Mike Mendelsohn/DC/USEPA/US@EPA

From: Steven Knott/DC/USEPA/US

Date: 07/16/2007 01:27PM

сс: Alaл Reynolds/DC/USEPA/US@EPA, Janet Andersen/DC/USEPA/US@EPA, Sharlene

Matten/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA, Susanne

Cerrelli/DC/USEPA/US@EPA

Subject: Re: MON 89034 & Possible SAP - Conversation with Steve Knott

Mike.

It appears we may be able to accommodate this topic December 12-14, 2007. We could start in the afternoon of the 12th, proceed through the 13th and part of the 14th (if needed). If you are interested in proceeding, please complete the attached profile sheet and return it to us by August 17.

Thanks.



Steve

Steven M. Knott **Executive Secretary** FIFRA Scientific Advisory Panel 202-564-0103 knott.steven@epa.gov

Mike,

At this point, it appears that November will not be feasible. I'll proceed with exploring options for December. I'll let you know as soon as I have any further information.

Thanks.

Steve

Steven M. Knott **Executive Secretary** FIFRA Scientific Advisory Panel 202-564-0103 knott.steven@epa.gov

Mike Mendelsohn/DC/USEPA/US

M ik ToSheryl Reilly/DC/USEPA/US@EPA, Alan e Reynolds/DC/USEPA/US@EPA, Susanne M Cerrelli/DC/USEPA/US@EPA en de ccJanet Andersen/DC/USEPA/US@EPA, Sharlene ls Matten/DC/USEPA/US@EPA, Steven oh Knott/DC/USEPA/US@EPA n/ D SubjectMON 89034 & Possible SAP - Conversation with Steve $\mathbb{C}/$ Knott U S E P A/ U S 06 /2 8/ 20

07 04 :3 2 P M

Sheryl,

Per your guidance, I talked with Steve Knott about SAP dates and a letter SAP for IRM issues surrounding MON 89034. I told Steve it was possible that we may not need the SAP, but that if so, it would probably be 1 day. Given the limited scope and time requirements, he said he may have a date in November (11/6) and that he would get back to me in about a week. He also said that if they did a November day that they would schedule 2 days as a buffer.

We also discussed the letter SAP option. Steve said that the letter SAP is really a letter peer review and not a SAP. This letter peer review is handled by the affected division (BPPD) with support from OSCP's SAP office. I'll update you when I hear from Steve.

Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
http://www.epa.gov/pesticides/biopesticides



Profile sheet.doc



To Susanne Cerrelli/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA

study prepared by Monsanto Company. 18 p.

bcc

Subject Re: Today's meeting @ MON89034 xmon 880 t7; and MON 89034 - follow-up

AR 469513 B Head, G. (2006) Insect Resistance Management Plan
for the Combined Trait Product MOON 89034 x MON
88017. Project Number: 06/RA/50/03. Unpublished

SRM

Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514

----Susanne Cerrelli/DC/USEPA/US wrote: ----

To: Mika Hunter/DC/USEPA/US@EPA, Rebecca Edelstein/DC/USEPA/US@EPA, Tessa Milofsky/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA

From: Susanne Cerrelli/DC/USEPA/US

Date: 04/19/2007 03:33PM

cc: Mike Mendelsohn/DC/USEPA/US@EPA, John Kough/DC/USEPA/US@EPA, Zigfridas

Vaituzis/DC/USEPA/US@EPA, Sharlene Matten/DC/USEPA/US@EPA

Subject: Today's meeting @ MON89034 xmon 88017; and MON 89034 - follow-up

Thanks everyone for their valuable input!

Here is a list of the current workload distribution for these new products:

Sharlene expressed the need for a SAP for the IRM issues after our meeting as Alan had mentioned.

Rebecca will be providing me a list of data and information she needs to wrap up her reviews. If anyone has noted any deficiencies at this time that they need addressed to complete their assessment please let me know.

The current phase 4 date for completion of Science reviews is October 24, 2007.

The date that our final decision is due is: June 10, 2008.

If you need anything for these reviews, please let me know.

Muchas Gracias! Mille Grazie! Danke! Merci!



Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)

[attachment "Table of studies WITH WHO AND CLASSIFICATION fin .doc" removed by Sharlene Matten/DC/USEPA/US]



Sharlene Matten/DC/USEPA/US 04/t9/2007 03:08 PM

- To Janet Andersen/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA
- cc Patricia Moe/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Susanne bcc

Subject SAP needed for IRM issues -- MON 89034 /2 lep toxin product: Lower Refuge Requirements requested -- no previous SAP for Bt corn to address this issue

Susanne conducted a MON 89034 team meeting today. She asked me to write up the issues concerning IRM and the need for a SAP meeting.

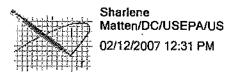
Monsanto has requested that MON 89034 have significantly lower refuge requirements for their two-toxin (for lep control -- a pyramid) product -- Cry1A.105 + Cry2Ab2. They are requesting a 5% structured non-Bt corn refuge in the Corn Belt (current for 1-tox lep product is 20%) and a 20% structured non-Bt corn refuge in cotton-growing areas (current for 1-tox lep product is 50%). These changes to the IRM requirements for BT corn are significant and a paradigm shift. Monsanto has submitted data to support their request and modeling These data need to be reviewed. The PRIA date for this action is 6/10/08.

No data have been submitted to support the popcorn use. Monsanto indicated a teleconference we had in February, 2007 that they do not even have a popcorn breeding program. There is no bridging information (IRM, expression, efficacy etc.) to support this use.

However, we received IRM data to support the sweet corn use and bridging arguments for the stacked product of Cry1A.105 + Cry2Ab2 + Cry3Bb1. These data were provided in March, 2007 after a 75-d deficiency letter was issued. I think Monsanto may intend to submit more sweet corn efficacy data needed for the IRM review. We may need to consider a renegotiation of the PRIA date to make up for the time lost- for the sweet corn use.

Sharlene R. Matten, Ph.D. **Biologist** USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514





To "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>

cc "BOGDANOVA, NATALIA N [AG/1000]"
<natalia.n.bogdanova@monsanto.com>, Alan
Reynolds/DC/USEPA/US@EPA, "REDING, H KEITH

bcc

Subject Re: Notes from the phone conversation on February 6, 2007

Natalia -- Thank you for the phone conversation. I have a few corrections to the notes you have provided. See my comments in green below. Thanks. SRM -----"BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com> wrote:

To: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>, Sharlene Matten/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA From: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com> Date: 02/08/2007 03:11PM

cc: "REDING, H KEITH [AG/1000]" <h.keith.reding@monsanto.com>, "SCHNEIDER, RUSSELL P]AG/1920]" <russell.p.schneider@monsanto.com>, "LAHMAN, LINDA K]AG/1000]" linda.k.lahman@monsanto.com>, Susanne Cerrelli/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA

Subject: Notes from the phone conversation on February 6, 2007

Sharlene.

Thank you for a very informative conversation yesterday. This message is to summarize the key points of the discussion to make sure we are in agreement.

In order to maintain sweet corn in Monsanto's application to register MON 89034 and MON 89034 x MON 88017 the following plan was proposed:

Sweet corn

- In order to obtain registration for sweet and popcorn a limited dataset should be provided.
- Leaf expression data for MON 89034 that will be provided by Monsanto should be sufficient to retain sweet corn in the application. EPA agrees we can collect expression data from the leaf of flowering MON 89034 sweet corn currently being grown in Hawaii. The leaf tissue is currently being harvested and the data is expected to be submitted to EPA in March 2007.
- Limited efficacy data (leaf disk insect bioassay using ECB and FAW) will be also collected and provided to the Agency within similar timeframe.
- If necessary, FAW and ECB efficacy can be confirmed in field efficacy trials at a single location in 2007-08.

Comments on bullets 2-4:

I didn't say just leaf expression data were adequate. What I said was that a leaf disc bioassay would be the first step one would need to support the sweet corn use. I then said that Monsanto would need both field efficacy data and field expression data and that

this could be done using the MON 89034 sweet corn currently being grown in Hawaii and such data would be submitted in Fall 2007. One would have to explain how these data would be representative of other mainland growing areas for sweet corn. In addition to leaf expression, one needs pollen expression, stalk expression, and ear expression for pests such as corn earworm, fall armyworm, and European corn borer (although I would expect this pest to be of lesser importance for sweet corn given where it is grown in the U.S.) at the appropriate plant developmental stages.

The timing of actions for sweet corn should not affect field corn registration PRIA date unless that data is submitted later that January 2008. Sharlene indicated that how the data submitted in March 2007 and later in 2007 to support the sweet corn use (insect resistance management issues) would affect the PRIA date needs to be discussed with Susanne Cerrelli and Mike Mendelsohn as well as any administrative or regulatory question.

Popcorn

- Popcom varieties of MON 89034 have not been developed yet.
- Both field efficacy and expression data would need to be submitted at some future date to address insect resistance management should MON 89034 be registered for popcorn use.
- Monsanto prefers that popcorn be retained in the registration request but as a
 condition of the registration, expression and efficacy data must be provided before
 MON 89034 can be commercialized in popcorn. Sharlene pointed out that without
 any data to support the popcorn use that this would be unlikely. She indicated
 that this issue should be discussed further with the RALs, Susanne Cerrelli and
 Mike Mendelsohn.

Please, let me know if we understood each other correctly. Thank you very much for your time and attention to MON 89034.

Best regards,

Natalia

----Original Message-----

From: BOGDANOVA, NATALIA N [AG/1000] Sent: Tuesday, February 06, 2007 11:19 AM

To: 'matten.sharlene@epa.gov'

Cc: REDING, H KEITH [AG/1000]; SCHNEIDER, RUSSELL P [AG/1920]

Subject: Information for today's discussion

Sharlene,

Here is the information we would like to discuss in the call this afternoon.

EPA Discussion Points for MON 89034 Sweet Corn

In a January 17, 2007 letter to Monsanto, EPA requested expression data on sweet corn and popcorn to perform an IRM assessment.

- We can provide expression data on MON 89034 sweet corn by mid-March 2007. We currently have MON 89034 sweet corn growing in Hawaii. The plants are at the flowering stage. We plan to take leaf samples from up to 10 plants and determine the dry weight expression of Cry1A.105 and Cry2Ab2.
- Field corn, popcorn and sweet corn all belong to the taxonomic group Zea mays subsp. mays; therefore, we expected that the expression level for sweet



corn and popcorn to be in the range seen for field corn.

- The proposed IRM plan for sweet corn requires no structured refuge but rather destruction of the stalks after harvest, before the larvae can mature. Therefore, the expression level of the proteins should have no impact on the overall IRM plan.
- MON 89034 has not been bred into popcorn at this time. However, we would like popcorn included on the label to allow for future use in popcorn.

Look forward to talk to you.

Natalia

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager Monsanto Company 800 North Lindbergh Blvd., 5t. Louis, MO 63167

Tel. (314) 694-3143 FAX (314) 694-3080

This e-mail message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

All e-mails and attachments sent and received are subject to monitoring, reading and archival by Monsanto. The recipient of this e-mail is solely responsible for checking for the presence of "Viruses" or other "Malware". Monsanto accepts no liability for any damage caused by any such code transmitted by or accompanying this e-mail or any attachment.



Sharlene Matten/DC/USEPA/US 07/23/2007 02:46 PM To Susanne Cerrelli/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA

CC

bcc

Subject MON 89034: IRM and Benefits studies plus comments on Public Interest Finding, sweet corn and popcorn uses

History:

This message has been forwarded.

Susanne -- I extracted, from an earlier table you sent to me, all of the IRM and efficacy and insect spectrum studies that Alan and I are reviewing. We are doing the IRM Plan review together. I am doing all of the efficacy and insect spectrum studies. I did not have all of the Submission information in all cases.

I do not have any document that would be used to make a Public Interest Finding should there be a conditional registrationunder 3(c)7(C). I would not assume that registration of MON 89034 will be an unconditional 3(c)5 registration; therefore, we need to make a Public Interest Finding and have a document from Monsanto that gives us the appropriate information to make such a finding.

In addition, we do not have sufficient information (expression and activity) to complete an IRM assessment for sweet corn. We have no information on popcorn. My recommendation is that Monsanto withdrawal both the sweet corn and popcorn uses until such information can be generated and submitted to EPA to support these uses

Sharlene Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514



Sharlene Matten/DC/USEPA/US 07/16/2007 04:06 PM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA

bcc

Subject Found a bit of bridging for sweet corn -- sweet corn still deficient

MRID 470794-02, p. 12, has a paragraph comparing the expression levels of the Cry1A.105 and Cry2Ab2 proteins in leaf tissues collected from MON 89034 sweet corn growin in Hawaii during 2007 to the levels previously reported for MON 89034 field corn grown in the Mainland U.S. (MRID 469514-03). The field corn data is represented for several locations while the sweet corn data is represented by one location in Hawaii (a suitable commercial source?). Additional sweet corn expression data and efficacy data are needed to support the sweet corn use.

There is no popcorn data of any kind. Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (751tP) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514



Sharlene Matten/DC/USEPA/US 07/16/2007 10:50 AM To Susanne Cerrelli/DC/USEPA/US@EPA

cc Alan Reynolds/DC/USEPA/US@EPA

bcc

Subject Submission numbers for MON 89034 and copies of studies

I am working at home today.

I would appreciate it if you could send me the Submission numbers for all the studies (IRM, efficacy, insect spectrum) that you gave me and Alan for MON 89034 or the stack. I think there would be two or three submission numbers. I also need a CD-ROM of of all of Monsanto's submissions. I need to add that information to the reviews.

Also, did you ever get a Public Interest Finding. I also see no data on sweet corn or popcorn -- no dose information or efficacy information or justification for sweet corn use or popcorn (some kind of written rationale). I know that in a teleconference call I had with Monsanto in February that they might have information to support the sweet corn use this Fall. What is the state of affairs for the sweet corn and popcorn uses?

Thank you for your help. Sharlene

Sharlene R. Matten, Ph.D. Biologist USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514 Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314)-694-3143 MONSANTO COMPANY 800 NORTH LINOBERGH BLVO ST. LOUIS, MISSOURI 63167 http://www.monsanto.com

May 25, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject:

Response to questions from EPA regarding insect-protected corn MON 89034

EPA File Symbol 524-LTL

Dear Dr. Reilly:

This letter is in response to the Agency's request from May 16, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in corn product MON 89034.

Responses to the Agency's questions are included in Volume 2 of this submission. This submission includes documents that have been classified as 'A'- non-confidential documents that can be released to the public. A pdf file is included.

Volume	Document	Category	Hard copy	pdf. file for E-docket
N/A	Cover Letter	A	7	√
N/A	Transmittal Document	Α	1	7
1	Administrative Materials for Submission of Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951400)	A	V	√
2	Responses to EPA Questions Regarding Application 524-LTL to Register Insect-protected Corn MON 89034 (MRID 46951400)	А	√	√

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natur W. Bylanone

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD

Russell Schneider, Monsanto Monsanto Regulatory Files



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 1300 I (Eye) Street, NW Suite 450 East Washington, DC 20005

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Registration of Insect-protected Corn MON 89034 (EPA File 524-LTL)

TRANSMITTAL DATE

May 25, 2007

MONSANTO REFERENCE No.

06-CR-I72-4

LIST OF SUBMITTED DOCUMENTS

Administrative Materials

Volume 1.	Appli	nistrative Materials for the Response to EPA Questions Regarding cation 524-LTL to Register Insect-protected Corn MON 89034 D 46951428)			
	MRIE	Number			
Volume 2.	Responses to EPA Questions Regarding Application 524-LTL to Registe Insect-protected Corn MON 89034 (MRID 46951428)				
	MRID	Number47140301			
Company Off	icial:	Natalia N Bogdanova, D.V.M. Date Regulatory Affairs Manager (314) 694-3143			
Company Nan	ne:	Monsanto Company			
Сотрапу Соп	ıtact:	Russell P. Schneider, Ph.D. Director, Regulatory Affairs (202) 383-2866			

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Re-classification of the information provided in the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 47079402)

Dear Dr. Reilly:

This letter is in response to conversations with the Agency regarding re-classification of information submitted on March 9, 2007 in the response to EPA questions regarding application to register insect-protected corn MON 89034 and MON 89034 x MON 88017.

By the way of this letter Monsanto amends the confidentiality claims for the information submitted with the above petitions to re-classify it from current category "A" (non-confidential documents that can be released to the public) to category "B" (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers). Monsanto considers this information to be a competitive advantage because it contains details concerning MON 89034 that are intended for the regulatory assessment and that could be potentially used by multinational companies to develop and register their products. Please consider the tables in Monsanto letters from March 9, 2007 revised as follows:

Monsanto Reference Numbers 04- CR-135E-3 04-CR-138E-3

Volume	Old Category	New Category	Document
N/A	A	Α	Cover letter
N/A	A	A	Transmittal document
1	Α	A	Administrative volume
]	С	C	Confidential statement of formula
2	A	В	Supplemental information
3	В	В	Efficacy report

Should you require any additional information regarding this letter please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Natal d. Bylanove

Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD Susanne Cerrelli, EPA/OPP/BPPD Russ Schneider, Monsanto Regulatory Archives

> Monsanto Reference Numbers 04- CR-135E-3 04-CR-138E-3

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143

May 11, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Re-classification of the information provided in the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 47079402)

Dear Dr. Reilly:

This letter is in response to conversations with the Agency regarding re-classification of information submitted on March 9, 2007 in the response to EPA questions regarding application to register insect-protected corn MON 89034 and MON 89034 x MON 88017.

By the way of this letter Monsanto amends the confidentiality claims for the information submitted with the above petitions to re-classify it from current category "A" (non-confidential documents that can be released to the public) to category "B" (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers). Monsanto considers this information to be a competitive advantage because it contains details concerning MON 89034 that are intended for the regulatory assessment and that could be potentially used by multinational companies to develop and register their products. Please consider the tables in Monsanto letters from March 9, 2007 revised as follows:



Dr. S. Reilly May 11, 2007

Volume	Old Category	New Category	Document
N/A	A	A	Cover letter
N/A	Α	A	Transmittal document
1	Α	A	Administrative volume
ī	С	C	Confidential statement of formula
2	Α	В	Supplemental information
3	В	В	Efficacy report

Should you require any additional information regarding this letter please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natalia N. Bogdanova, D.V.M.

Natal N. Bylan

cc: Mike Mendelsohn, EPA/OPP/BPPD Susanne Cerrelli, EPA/OPP/BPPD Russ Schneider, Monsanto

Regulatory Archives

Deficiencies in Monsanto's submissions for registration of MON 89034 and MON 89034 x MON 88017

Monsanto needs to address the following:

- 1. Validated detection method protocols and independent lab validations of the detection methods for Cry1A.105 and Cry2Ab2 in corn need to be submitted.
- 2. Plant-produced Cryl A.105 shows both a higher-molecular weight immunoreactive band and lower molecular weight immunoreactive bands in the western blot analysis in addition to the full-length protein. These additional bands appear to be absent in the E. coli-produced protein preparation. Monsanto should address whether these differences are a result of protein purification or whether these different molecular weight proteins are likely present in the plant. Monsanto should also explain why use of the E. coli protein as a surrogate for safety testing is appropriate, given the differences in the protein preparations.
- 3. Provide the SOPs cited in MRIDs 46951302 (MSL-20145, Study 06-01-50-03), 46951402 (MSL-20311, Study 05-01-39-12), 46951303 (MSL0020479), 46951403 (Study 05-01-39-32, MSL 20285).
- 4. Discuss determination of equivalence between microbially-produced and plant-produced Cryl A.105 using the bioactivity assay (described in MR1D 46694604). Were statistics used? Why was the acceptance criteria determined to be <4 fold difference between the mean EC₅₀ values in the corn earworm diet-incorporation insect biassay?
- 5. Explain the discrepancy in the EC₅₀ definitions given on pages 11 and 8 in MRID 46951405.

Also, we request electronic copies of the following studies: MRIDs 46951403 (Study 05-01-39-32, MSL 20285)—need tables only, 46951404 (MSL-20071)—need figures only, 46951405 (MSL-20132; Study 05-01-39-23), 46951407 (MSL-19931; Study 05-01-62-04)—need figures only, 46951303 (MSL0020479)—need tables only, 46951408 (MSL-19930; Study 05-01-62-03)—need figures only, 46951409 (MSL-19938; Study 05-01-62-05)—need figures only, 46951402 (MSL-20311, Study 05-01-39-12)—need figures only.

Janet Andersen/DC/USEP A/US

To Rebecca Edelstein/DC/USEPA/US@EPA

05/21/2007 02:18

cc John Kough/DC/USEPA/US@EPA

PΜ

Subject Re: analytical detection method-- update

We actually have regulations in place that say there should be an analytical method for any tolerance or tolerance exemption we put in place. Therefore, let's continue to have methods and let's allow a DNA based method.

Rebecca Edelstein/DC/USEPA/U S

05/22/2007 08:55 AM

To Susanne Cerrelli/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA

bcc

Subject Fw: analytical detection method-- update

Susanne,

I think we need Monsanto to submit an analytical method for detecting Cry1A.105 (DNA based or protein based). Right now, MON 89034 is the only event in corn that produces Cry2Ab2, so if Cry2Ab2 is detected, Cry1A.105 would also be present. However, the detection methods are needed for our tolerance exemptions, and we have separate tolerance exemptions for Cry2Ab2 and Cry1A.105. Also, the tolerance exemptions are not product specific, so in the future, there may be another product that produces Cry2Ab2 in corn; therefore, we can't rely on the Cry2Ab2 method to detect Cry1A.105. Please let me know if you have any questions.

Thanks,

Rebecca

----- Forwarded by Rebecca Edelstein/DC/USEPA/US on 05/22/2007 08:50 AM -----

Janet

Andersen/DC/USEPA/U

S

05/2 t/2007 03:03 PM

To Rebecca Edelstein/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA

Subject Re: analytical detection method-- update 🖹

Won't Cry1A:105 be a new ai? Have a unique identifier? If so, it needs a method or maybe the chimeric needs a method. Just because they are the only ones right now with Cry2Ab2 does not mean that will always be so.

Rebecca Edelstein/DC/USEPA/US

Rebecca

Edelstein/DC/USEPA/U

S

05/21/2007 02:38 PM

To Janet Andersen/DC/USEPA/US@EPA

cc John Kough/DC/USEPA/US@EPA

Subject Re: analytical detection method-- update

Janet,

Thanks for the quick response. Monsanto is now saying that they don't want to submit the DNA based method. Instead, they want the lateral flow method for Cry2Ab2 to be sufficient, since MON 89034 is the only com product that produces Cry2Ab2. The product also contains a chimeric protein, Cry1A.105, but because MON 89034 is the only corn event with Cry2Ab2, detection of Cry2Ab2 enables MON 89034 to be identified. Do you think one method is sufficient? Or do we need a method that is specific for Cry1A.105?

Rebecca
Janet Andersen/DC/USEPA/US





Susanne Cerrelli/DC/USEPA/US 05/03/2007 08:50 AM To Sharlene Matten/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA

cc Mike Mendelsohn/DC/USEPA/US@EPA

bcc

Subject memorandum of understanding dated February 5, 2007 from Monsanto - Comments from EPA

Are there any additional comments that we should send monsanto concerning their February 5, 2007 letter that followed our meeting on January 25, 2007? Sharlene gave me the following feedback yesterday. please let susanne know if there are additions or corrections to the below item.

We wish that the following item be corrected that is present in Monsanto's February 5, 2007 letter concerning "Memorandum of understanding; EPA Petition numbers 6F7142 and 6F7143; EPA File symbols: 524-LTA and 524-LTL."

For item 2 we wish to make the following correction. Separate information needs to be developed to support the popcorn use. We disagree that expression data (information) developed for sweet corn can be applied to popcorn.

Please note we plan to add some items to today's biotech meeting.

- (1) DNA vs ELISA quantification (feedback what is EPA's purpose of validation when have tol. exemption)?
- (2) Should we renegotiate dates when company gives additional info later that we need (What is Agency Policy @ late submissions and PRIA dates)?
 - (a) MARCH 7 irm RESPONSE
 - (b) Sweet corn expression data that is being developed still

Thanks!

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)





Susanne Cerrelli/DG/USEPA/ US 04/23/2007 11:03

To "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>

cc Mike Mendelsohn/DC/USEPA/US

bcc

Subject Re: Notes from the phone conversation on February 6, 2007

Dear Dr. Natalia Bogdanova,

During our preliminary evaluation of MON 89034 and MON 89034 x MON88017, several items were identified that are needed to complete our evaluation. in order to complete the evaluation process, we wish to notify you of noted deficiencies in Monsanto's submissions.

Monsanto needs to address the following:

- 1. Validated detection method protocols and independent lab validations of the detection methods for Cry1A.105 and Cry2Ab2 in corn need to be submitted.
- 2. Plant-produced Cry1A.105 shows both a higher-molecular weight immunoreactive band and lower molecular weight immunoreactive bands in the western plot analysis in addition to the full-length protein. These additional bands appear to be absent in the *E. coli*-produced protein preparation. Monsanto should address whether these differences are a result of protein purification or whether these different molecular weight proteins are likely present in the plant. Monsanto should also explain why use of the *E. coli*-protein as a surrogate for safety testing is appropriate, given the differences in the protein preparations.
- 3. Provide the SOPs cited in MRIDs 46951302 (MSL-20145, Study 06-01-50-03), 46951402 (MSL-20311, Study 05-01-39-12), 46951303 (MSL0020479), 46951403 (Study 05-01-39-32, MSL 20285).
- 4. Discuss determination of equivalence between microbially-produced and plant-produced Cry1A.105 using the bloactivity assay (described in MRID 46694604). Were statistics used? Why was the acceptance criteria determined to be <4 fold difference between the mean EC_{so} values in the corn earworm diet-incorporation insect bloassay?
- Explain the discrepancy in the EC₅₀ definitions given on pages 11 and 8 in MRID 46951405.

Also, we request electronic copies of the following studies: MRIDs 46951403 (Study 05-01-39-32, MSL 20285)?need tables only, 46951404 (MSL-20071)?need figures only, 46951405 (MSL-20132: Study 05-01-39-23), 46951407 (MSL-19931; Study 05-01-62-04)?need figures only, 46951303 (MSL0020479)?need tables only, 46951408 (MSL-19930; Study 05-01-62-03)?need figures only, 46951409 (MSL-19938, Study 05-01-62-05);need figures only, 46951402 (MSL-20311, Study 05-01-39-12)?need figures only.



Your efforts to address these in a timely manner, would be greatly appreciated. Of course if this is not possible, the PRIA date may need to be renegotiated. Please note that additional deficiencies may be noted in the future as the evaluations are not completed at this time. If you have any questions concerning this request, please contact Susanne Cerrelli at 703-308-8077.

Susanne Cerrelli

Regulatory Action Leader Microbial Pesticides Branch Biopesticides Pollution Prevention Division (7511P)

703-308-8077(w)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JAN 1 7 2007

Dr. Natalia N. Bogdanova Regulatory Affairs Manager Monsanto Company 800 N. Lindberg Blvd. St. Louis, MO 63167

Dear Dr. Bogdanova:

Subject: MON89034 x MON 88017 (Cry1A.105, Cry2Ab2 and Cry3Bb1) Corn and

MON89034 (Cry1 A.105, and Cry2 Ab2) Corn EPA Petition Numbers: 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL

Your applications as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for this action category (B81 twice) by June 10, 2008. Upon review of the subject applications, we have determined that they are incomplete.

The applications will be kept open for a period of 75 days from the date of this letter to give you an opportunity to address the deficiencies listed below. If you find that you need more time to satisfy the requirements, you must request an extension in advance of the 75-day compliance date, and commit to satisfy the deficiencies within a reasonable, stated, period of time. Your time extension request must also include an explanation of why additional time is required. If you do not comply with this procedure, the Agency may administratively withdraw your application from further consideration and retire this file without further notice to you, in accordance with 40 CFR 152.105. Once this is done, you will have to submit a complete new application should you wish to pursue these actions.

Based upon your response, we may need to renegotiate the current PRIA date of June 10, 2008. In the interim period, we are placing the data received thus far into scientific review.

The following deficiencies must be addressed:

- 1) The insect resistance management (IRM) package for MON 89034 X MON 88017 is deficient. There is no bridging rationale provided that links the dose and efficacy of the stacked product to that of each single gene product for each target pest as justification for the proposed IRM plan for the stacked product.
- 2) Expression data are necessary for popcorn and sweet corn in order to perform the IRM assessment.

CONCURRENCES								
SYMBOL > 7511 75119 75	51H							
SURNAME > Sternell moder P.	77.8							
DATE 1/1/2007 1/1/0)	1790	(205)						

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

- 3) The tolerance petitions request that 40 CFR Part 180 be amended to remove time limitations for the temporary exemptions from the requirement of a tolerance. These need to be modified so that you request to amend 40 CFR Part 174.453 and 174.464 to make them permanent exemptions from the requirement of a tolerance. Temporary tolerance exemptions not only have time limitations, but are linked to specific experimental use permits.
- 4) Submit revised labeling consistent with that approved for your MON 88017 product. OECD unique identifiers should appear in the ingredient name for events MON 88017 and MON 89034 and the directions for use and insect resistance management sections should be consistent. Field corn, popcorn, and sweet corn should also be addressed.
- 5) Marker proteins and inerts need to be listed on the confidential statement of formula (CSF).

On December 14, 2006, your associate, Dr. Russ Schneider indicated that he was interested in meeting with our staff to address any questions that we may have concerning these pending applications. In addition to the required information listed above, we wish to inform you of materials that would assist in expediting the review of your submission, and questions that we wish to discuss at such a meeting.

Concerning the IRM assessment we have the following questions:

- 1) What are the relative contributions of each toxin (i.e., dose of each toxin and selection)? Explain "dose" studies and your assumptions about dominance and inheritance of resistance.
- 2) How is Roush's model used for predicting resistance (relative contribution of each toxin) to ECB? What are the assumptions?
- 3) What information, relative to each toxin, is being fitted to the Monsanto revised bollworm model?

A CD with writable "MS word" files of the submitted data would facilitate incorporating tables, graphs, and other data from your submissions in our reviews.

Please contact Susanne Cerrelli of my staff at (703) 308-8077 should you have any questions or wish to schedule a meeting.

Sincerely,

Sheryl Rellly, Chief

Microbial Pesticides Branch Biopesticides and Pollution

Prevention Division (7511P)

Sharlene Matten/DC/USEPA/US 04/19/2007 03:08 PM

To Janet Andersen/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

cc Patricia Moe/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA, Susanne

hec

Subject SAP needed for IRM issues - MON 89034 /2 lep toxin product: Lower Refuge Requirements requested - no previous SAP for Bt corn to address this issue

Susanne conducted a MON 89034 team meeting today. She asked me to write up the issues concerning IRM and the need for a SAP meeting.

Monsanto has requested that MON 89034 have significantly lower refuge requirements for their two-toxin (for lep control -- a pyremid) product -- Cry1A.105 + Cry2Ab2. They are requesting a 5% structured non-Bt corn refuge in the Corn Belt (current for 1-tox lep product is 20%) and a 20% structured non-Bt corn refuge in cotton-growing areas (current for 1-tox lep product is 50%). These changes to the IRM requirements for BT corn are significant and a paradigm shift. Monsanto has submitted data to support their request and modeling These data need to be reviewed. The PRIA date for this action is 6/10/08.

No data have been submitted to support the popcorn use Monsanto indicated a teleconference we had in February, 2007 that they do not even have a popcorn breeding program. There is no bridging information (IRM, expression, efficacy etc.) to support this use.

However, we received IRM data to support the sweet corn use and bridging arguments for the stacked product of Cry1A.105 + Cry2Ab2 + Cry3Bb1. These data were provided in March, 2007 after a 75-d deficiency letter was issued. 1 think Monsanto may intend to submit more sweet corn efficacy data needed for the IRM review. We may need to consider a renegotiation of the PRIA date to make up for the time lost- for the sweet corn use.

Sharlene R. Matten, Ph.D. **Biologist** USEPA/OPP/BPPD (7511P) 1200 Pennsylvania Ave., NW Washington D.C. 20460 703-605-0514



Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314)-694-3143

Mansanto Campany
1300 I (Eye) Street, NW
Suite 450 East
Washington, D.C. 20005
PHONE (202) 383-2866
FAX (202) 789-1748
http://www.monsento.com

March 9, 2007

Document Processing Desk (PETN)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subject:

Ì

Response to the letter from EPA RE: MON 89034 (Cry1A.105 and Cry2Ab2)

Corn and MON 89034 × MON 88017 (Cry1A.105, Cry2Ab2, Cry3Bb1) Corn

EPA Petition Numbers 6F7142 and 6F7143 EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly:

This letter is in response to the Agency's request from January 17, 2007 to address questions pertaining to Monsanto's application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in the corn product MON 89034 and MON 89034 × MON 88017. Some of these questions were clarified at the Monsanto/EPA meeting held on January 25, 2007.

Responses to Agency's questions included in Volume 2 and in a confidential attachment to the Administrative volume. Additional efficacy data is provided as Volume 3. This submission includes the following documents that have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf and/or Word files are included on a CD-ROM.



Volume	Category	tegory Document		.pdf or Word file	
N/A	A	Cover letter	V	√	
N/A	A	Transmittal document	1	√	
1	A	Administrative volume	V		
I	С	Confidential statement of formula	1		
1	A	Administrative volume (redacted copy)		√	
2	A	Supplemental information	1	√	
3	В	Efficacy report	√		

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

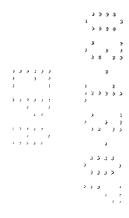
Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD

Natah N. Bylanore

Russell Schneider, Monsanto Monsanto Regulatory Files



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

EPA File 524 - LTL and 524-LTA

TRANSMITTAL DATE

March 9, 2007

MONSANTO REFERENCE No.

06-CR-172E-2

Page 1 of 2

Monsanto Company

04-CR-172E-2 Transmittal Document

210

LIST OF SUBMITTED DOCUMENTS

<u>Administrat</u>	ive Mat	<u>erials</u>						
Volume 1.	lnfo LTL	ninistrative Materials for the Submission of Strmation to Address EPA Questions Regardin, and 524-LTA to Register Insect-protected ON 89034 x MON 88017 (MRID 46951400 and	ng Applications 524- Corn MON 89034 and					
	MRIE	Number	······					
Volume 2.	Quest Insect	Bogdanova. 2006. Supplemental Informations Regarding Applications 524-LTL and 5 protected Corn MON 89034 and MON 8903 46951400 and 46951300)	24-LTA to Register					
	MRIE	MRID Number						
Volume 3.	MON	ick et al., 2006. Assessment of the efficacy 89034, MON 89034 x MON 88017, and MO trajor insect pests in the field trials conductions.	ON 89034 x NK603					
	MRIE	Number						
Company Off	ficial:	Natal N. Bylana	3/9/07					
		Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143	Date	33				
Company N	ame:	Monsanto Company	, s	3 3 3 3				
Company Contact:		Russell P. Schneider, Ph.D.	9 7 3 7 3 5 1 2 5 1 2 5	3				

Monsanto Company

04-CR-I72E-2 Transmittal Document

Director, Regulatory Affairs

(202) 383-2866

Page 2 of 2



Title

Administrative Materials for the Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

Author

Natalia N. Bogdanova, D.V.M.

Registrant Submission Date

March 9, 2007

Registrant Submitting

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

Registrant Document No.

registi ant Document 140.		
04-CR-172E-2		2 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3
V		\$.
	3 3 3 3 3 3 3 3 5 3 5	3 4
Volume 1 of 3	337 4 3 8) > 3 2 2 3
	7 1 1 7 7	3 7 3 3 5 3
	,,,,,	3 3 3 3 3
		3 3 3 3 3 3 3 3 3
		> = > ;

Monsanto Company

04-CR-172E-2

Page 1 of 20



STATEMENT OF NO DATA CONFIDENTIALITY CLAIM

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B), or (C).

Monsanto submits this material to the United States Environmental Protection Agency specifically under the requirements set forth in FIFRA as amended, and consent to the use and disclosure of this material by EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to EPA.

Company:

Monsanto Company

Company

Agent:

Natalia N. Bogdanova, D.V.M.

Regulatory Affairs Manager

Date:

March 9, 2007

Page 2 of 20

GLP COMPLIANCE STATEMENT

This volume provides the administrative materials for the submission of supplemental information to address EPA questions regarding applications 524-LTL and 524-LTA to register insect-protected corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300) and therefore were not developed in compliance with 40 CFR Part 160.

Submitter

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

Date

}

)

Page 3 of 20

Table of Contents

	Page
Title	1
Statement of No Data Confidentiality Claim	2
GLP Compliance Statement	3
Table of Contents	4
Administrative Materials	5
EPA Form 8570-1 Application to Register	7 8
Product label	



Administrative Materials

Application to Register (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

Page 5 of 20

Please read instructions on rever	se before completing for	m.	Form Approve	ed. OMB No.	2070-0060.	Approval Expires	2-28-95
		United States	•			Registration	OPP Identifier
SEPA Environmental Protect				:v		Amendment	Number
	Washington DC 20460						
				<u></u>		Other	
	Applic	cation for F	Pesticide -	Section I			
1	Product Number		2. EPA Produc			3. Propos	sed Classification
	4-LTL and 524-LTA	<u>4</u>		Sheryl Rei	lly		
	Product (Name)	10015	PM#	0.0		⊠ Nor	ne Restricted
MON 89034 and M				90	·-····		······································
5. Name and Address of	Applicant <i>(Include ZIP C</i> ato Company	ode)					ion 3(c)(3)(B)(i), my
	Lindbergh Blvd.		EPA Reg. No			tion and labeling to	:
	s, MO 63167						
	his is a new address		Product Name	e		***************************************	
Check ii i	11/3 /3 /3 /10/4 /3/01/03/3	Sect	ion – II				
<u> </u>		***************************************	1011 11	Final printed	l lahels in r	senonee to	
l _.	Amendment – Explain t	pelow.		Agency lette		еэропэе со	
Resubm	ssio <i>n in r</i> esponse to Age	incy letter dated		"Me Too" Ap	oplication.		
	Notification – Explain b	elow	$\overline{\boxtimes}$	Other - Exp	lain below.		
			ك	•			
Submission of Supplementa(Int	Explanation: Use a formation to Address						egister Insect-
protected Corn MON 89034 and	MON 89034 x MON	88017 (MRID	46951400 and	46951300)		3 0 2 1 2 1 1 1 to 1 to	5,5to, 111300t
		Sect	ion – III				
	1. M	aterial This Prod	tuct Will Be Paci	kaged (n:		-	
Child-Resistant Packaging	Unit Packaging	1	Water Soluble Pa	ackaging	2. Ţ	ype of Container	
Yes*	Yes	-	Yes			Melal	
L No	No No		No			Plaslic	
* Certification must	If "Yes"	No. per	If "Yes"	No. per		Glass	
be submitted	Unil Packaging wgl.	Container	Package wgt.	Container		Paper Other	
					/So	Other ecify)	
3. Location of Net Content	ts Information	4. Size(s) Retai	l Container			n of Label Direction	าร
Label T	Container				On Li	abel	
			Various		On L	abeling accompany	ing product
6. Manner in Which Label is	Affixed to Product	Lilhograpi	n	Other			
		Paper glue	ed				<u> </u>
		Slenciled					
			on – IV				
	lete ilems directly below	I	of individual to be	contacted, if r	necessary, I		······································
Name Russell P. S		Tille	Director, Regu	datom, Affr	ire		Indude Area Code) 883-2866
Russeii I. B		Certification	Director, Regu	Balury Ariz	1115	' ` ` 	3-2-5-2
I certify that the statements I have made on this form and all attachment						te.	3, Dale,Application 3 Rèce)ved
l acknowledge that any kr	l acknowledge that any knowingly false or misleading stalement ma bolh under applicable law			by fine or impr	isonment o	1,2,2,	\$ \$10 M\$VOG
		···		<i>3</i>	(Stamped)		
2. Signatu	ire Anna in te	3. Title	Damilatani i	Affaira Nda-	nager Nager	, , , , , , , , , , , , , , , , , , , ,	
Natul M. Bylacione			Regulatory A	ngrans ivial	rakei.	- :- :- :- :- :- : : : : : : : : : : :) 3 3
4. Typed No		5. Dale	Maral 0 00	37		19/99	3
Natalia N. Bogdanova	Tel. (314) 694-31	4.7	March 9, 20	J (Į.	*>3.3
FDA Form 9670 4 /Pau 2 94) Pa	aviate aditions are abo		Nhite EDA Cile		D 37-11-	Ĺ	<u> </u>

217

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}



2	F	DΔ
		ГМ

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.

WASHINGTON, D.C. 20460						
Certification with Respect to Citation of Data						
Applicant's/Registrant's Name, Address, and Telephone Number:		EPA Registration Number / Fite Symbol:				
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO (314) 694-3143	63167 Tel.	524-LTL and 524-LTA				
Active Ingredient)s) and/or representative test compound(s):		Date:				
Bacillus Ihuringiensis Cry1A.105 and Cry2Ab2 proteins and the genetic necessary for their production in corn	material	March 9, 2007				
General Use Pattern(s) (list all those claimed for this product using 40 C	FR Part 158:	Product Name:				
Terrestrial field crop	!	> Lepidopteran-Protected Com (MON 89034)				
		➤ Lepidopteran and Coleopteran protected and glyphosate tolerant corn (MON 89034 x MON 88017)				
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption						
I am responding to a Data-Call-in Nolice, and have included w form should be used for this purpose).	ith this form a list of	companies sent offers of compensation (the Data Matrix				
Section I: METHOD OF DATA	SUPPORT (Cl	neck one method only)				
I am using the cite-all method of support, and have included we this form a list of companies set offers of compensation (the Data Matrix Form should be used for this purpose).	unde com	using the selective method of support (or cite-all option er the selective method), and have included with this form a pleted list of data requirements (the Data Matrix form must sed).				
Section II: GEN	ERAL OFFER	TO PAY				
[Required if using the cite-all method or when using the cite-al						
i hereby offer and agree to pay compensation, to other person	is, with regard to the	approval of this application, to the extent required by				
Section III: CERTIFICATION						
I certify that this application for registration, this form for reregistration, or this Data-Catl-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Catl-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.						
I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.						
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.						
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.						
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false of misleading statement may be punishable by fine or imprisonment of both under the applicable law.						
Signature	Typed or Printed Name and Title					
Natur W. Bylacia	Natalia N. Bogdanova, D.V.M., Regulatory Affairs Manager					

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0040,



Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Roduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DATA	A MATRIX				
Dale: March 9, 2007 Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63 t67			EPA Reg. No./File Sym LTA	EPA Reg. No./File Symbol: 524-LTL and 524-LTA		
			Product: MON 89034 a	Product: MON 89034 and MON 89034 × MON 88017		
Ingredient Bacilius thui MON-89Ø34-3)	ringlens is Cry1A.105 and Cry2Ab2 proteins and the genetic materia	II (vector PV-ZMtR24	5) necessary for their production in MC	N 89034 corn (OECI	O Unique Identifier:	
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
	N.N. Bogdanova, 2007. Administrative Materials for Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission	
	N. N. Bogdanova. 2006. Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)		Monsanto Company	OWN	This Submission	
	Headrick et al., 2006. Assessment of the efficacy of insect-protected corn MON 89034, MON 89034 x MON 88017, and MON 89034 x NK603 against major insect pests in the field trials conducted in the U.S. during 2005		Monsanto Company	OWN	This Submission	
Signature Works	ih W. Bylaciona		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date March 9, 2007		

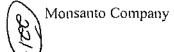


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W. Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this colle response for reregistration and special review activities, including time for re- other aspect of this collection of information, including suggestions for reduci 401 M Street, S.W., Washington, DC 20460. Do not send the form to this add	ading the instructions and completing ing the burden to: Director, OPPE In	g the necessary forms. Send comr	nents regarding the bur	den estimate or any	
	DATA MATRIX				
Pate: March 9, 2007			No./File Symbol: 524-L1 FA	L Page 1 of 1	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167		Product: MON 89034 and MON 89034 x MON 88017			
Ingredient Bacilfus thuringiensis Cry1A.105 and Cry2Ab2 Proteins and the Identifier: MON-89Ø34-3)	ne Genetic Materiat (Vector PV-ZMtF	R245) Necessary for their Production	en in MON 89034 com (OECD Unique	
Guideline Reference Number Guideline Study Name	MRtD Number	Submitter	Status	Note	
		Monsanto Company	OWN	This Application	
		Monsanto Company	OWN	This Application	
		Monsanto Company	OWN	This Application	
Signalure Nature W. Papelace	72-0	Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date March 9, 2007		



\$EPA

MON 89034

Corn Borer -Protected Corn

(OECD Unique Identifier: MON-89Ø34-3)

This product is effective in controlling damage caused by corn borer, fall armyworm, corn earworm and corn rootworm larval feeding on stalks, leaves, and ears of field corn, popcorn, and sweet corn.

Active Ingredient:

Other Ingredients: none

Percentage (wt/wt) on a dry weight basis whole plant (forage).

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS

EPA Registration No. 524-LTL

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167



DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. The following information regarding commercial production must be included in the MON 89034 corn Technology Use Guide (TUG) and the Insect Resistance Management (IRM) Guide.

MON 89034 protects corn crops from leaf, stalk, and ear damage caused by corn borers. In order to minimize the risk of these pests developing resistance to MON 89034 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

INSECT RESISTANCE MANAGEMENT

Growers of MON 89034 must adhere to all of the following refuge requirements.

Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-lepidopteran-protected com as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-lepidopteran-protected corn as a structured refuge.

The refuge must be placed within ½ mile (within ¼ mile preferred) of the MON 89034 field. When planting the refuge in strips, the strips must be at least four rows wide.

Insecticide treatments for control of European corn borer, southwestern corn borer and corn earworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides cannot be applied to the refuge acres.

These refuge requirements will not apply to operations engaged in the propagation of inbred and hybrid seed corn.

CORN INSECTS CONTROLLED OR SUPPRESSED

MON 89034 field corn, sweet corn and popcorn produce the *Bt* proteins, Cry1A.105 and Cry2Ab2, that control or suppress the following lepidopteran and coleopteran insects:

European corn borer (Ostrinia nubilalis)
Corn earworm (Helicoverpa zea)
Fall armyworm (Spodoptera frugiperda)
Southwestern corn borer (Diatrea grandiosella)
Southern cornstalk borer (Diatraea crambidoides)
Sugarcane borer (Diatrea saccharalis)

MON 89034 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. Patents: 38-21(52905); 38-21 (53618).



MON 89034 × MON 88017

Corn Borer and Rootworm-Protected Corn (OECD Unique Identifier: MON-89Ø34-3 × MON-88Ø17-3)

This product is effective in controlling damage caused by corn borer, fall armyworm, corn earworm and corn rootworm larval feeding on stalks, leaves, ears, and roots of field corn, popcorn and sweet corn.

Active Ingredient:

Other Ingredients:

Percentage (wt/wt) on a dry weight basis whole plant (forage).

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS

EPA Registration No. 524-LTA

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167



DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling. The following information regarding commercial production must be included in the MON 88017 corn Technology Use Guide (TUG) and Insect Resistance Management (1RM) Guide.

MON 89034 × MON 88017 protects corn crops from leaf, stalk, and ear damage caused by corn borers and root damage caused by corn rootworm larvae. In order to minimize the risk of these pests developing resistance to MON 89034 x MON 88017 corn, an insect resistance management plan must be implemented which includes planting of a structured refuge.

INSECT RESISTANCE MANAGEMENT

For MON 89034 × MON 88017 corn grown in non-cotton growing regions of the United States, two options for deployment of the refuge are available to growers. Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-lepidopteran-protected corn as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-lepidopteranprotected corn as a structured refuge.

Growers may choose to plant a common refuge for both corn borer and corn rootworm pests, or they may choose to plant separate corn borer and corn rootworm refuges. For growers who do not typically apply insecticides for control of corn borers, the common refuge option may be appropriate. In regions where corn borer infestations are high, growers may benefit from planting separate corn borer and corn rootworm refuges. This option is appropriate when corn borer infestations are expected to exceed economic thresholds. The benefit of a separate refuge allows the grower to manage corn borer in both the corn rootworm refuge (by planting corn borer-protected corn in this refuge) and corn borer refuge (by applying conventional insecticides) without having to spray the entire MON 89034 × MON 88017 field (Common Refuge Option: Refuge Management).

1. Common Refuge Option

- a) Refuge Size Growers must plant a minimum of 20% non-Bt corn as a structured refuge. This refuge size applies throughout the US.
- b) Refuge Placement and Configuration The refuge must be placed within or adjacent to the MON 89034 × MON 88017 field. Refuge deployment options include continuous blocks adjacent to the MON 89034 × MON 88017 field, continuous blocks within the MON 89034 × MON 88017 field, strips around the MON 89034 × MON 88017 field, or strips within the MON 89034 × MON 88017 field. When planting the refuge in strips, the strips must be at least four rows wide.
- c) Refuge Management The refuge and MON 89034 × MON 88017 acres should be managed under comparable agronomic regimes. In MON 89034 × MON 88017 fields where corn is cropped continuously, refuge acres should be planted in a continuous cropping regime. The refuge may be placed on first-year corn



Page 14 of 20

Monsanto Company 04-CR-172E-2 acres only if the MON 89034 × MON 88017 corn is planted on first-year corn acres. Growers have the option of applying conventional insecticides to the corn refuge for control of corn rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt insecticide to control late season pests such as corn borer or corn rootworm adults. However, if growers opt to treat the refuge while adult corn rootworm are present, then the MON 89034 × MON 88017 acres must be treated in a like manner. Microbial Bt insecticides cannot be applied to the refuge acres.

2. Separate Refuge Option

The Corn Rootworm Refuge:

- a) Refuge Size Growers must plant a minimum of 20% non-corn rootworm-protected corn (i.e., corn not containing Cry3Bb1 protein) as a structured refuge. This refuge size applies throughout the US. This refuge should be planted with corn borer-protected corn (e.g., MON 89034). A separate corn borer refuge also must be established (see Corn Borer Refuge below).
- b) Refuge Placement and Configuration The refuge must be placed within or adjacent to the MON 89034 × MON 88017 field. Refuge deployment options include continuous blocks adjacent to the MON 89034 × MON 88017 field, continuous blocks within the MON 89034 × MON 88017 field, strips around the MON 89034 × MON 88017 field, or strips within the MON 89034 × MON 88017 field. When planting the refuge in strips, the strips must be at least four rows wide.
- c) Refuge Management The refuge and MON 89034 × MON 88017 acres should be managed under comparable agronomic regimes. In MON 89034 × MON 88017 fields where corn is cropped continuously, refuge acres should be planted in a continuous cropping regime. The refuge may be placed on first-year corn acres only if the MON 89034 × MON 88017 corn is planted on first-year corn acres. Growers have the option of applying conventional insecticides or seed treatments to the corn refuge for control of corn rootworm larvae and other soil pests. The refuge can also be treated with a non-Bt insecticide to control late season pests. However, if growers opt to treat the refuge while adult corn rootworm are present then the MON 89034 × MON 88017 acres must be treated in a like manner. Microbial Bt insecticides cannot be applied to the refuge acres.

The Corn Borer Refuge:

- a) Refuge Size Growers in counties in which no cotton is grown (e.g., counties in the northern corn belt) must plant a minimum of 5% non-Bt corn as a structured refuge. Growers in counties in which cotton is grown must plant a minimum of 20% non-Bt corn as a structured refuge.
- b) Refuge Placement and Configuration The refuge must be placed within ½ mile (within ¼ mile preferred) of the MON 89034 × MON 88017 and corn rootworm refuge fields. When planting the refuge in strips, the strips must be at least four rows wide.

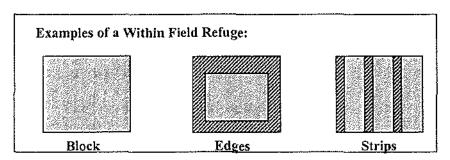
936)

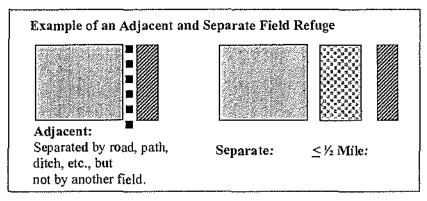
c) Refuge Management - Growers have the option of applying conventional insecticides or seed treatments to the refuge for control of corn rootworm larvae. Insecticide treatments for control of European corn borer, southwestern corn borer and corn earworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial Bt insecticides cannot be applied to the refuge acres.

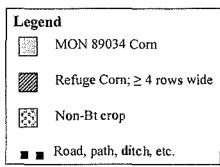
These refuge requirements will not apply to operations engaged in the propagation of inbred and hybrid seed corn.



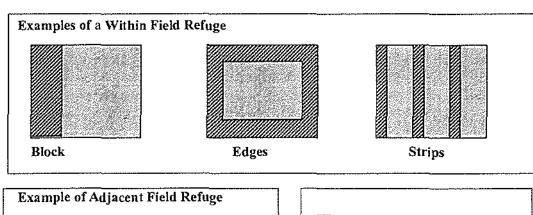
MON 89034 corn refuge placement and configuration options:

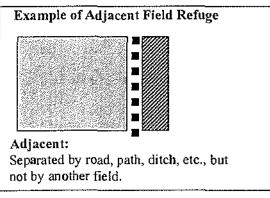


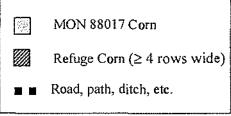




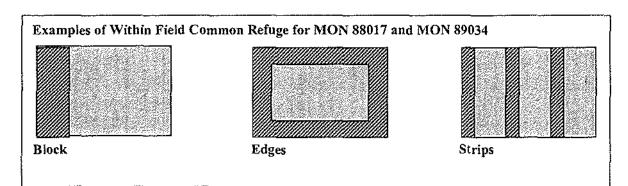
MON 88017 corn refuge placement and configuration options:

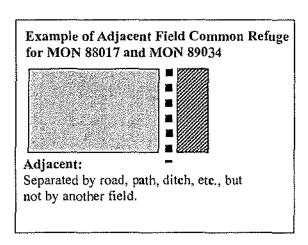




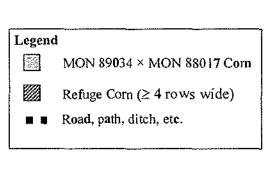


MON 89034 \times MON 88017 corn: Common refuge placement and configuration options for MON 88017 and MON 89034



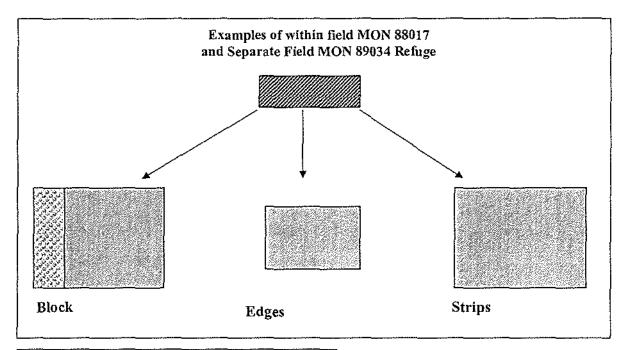


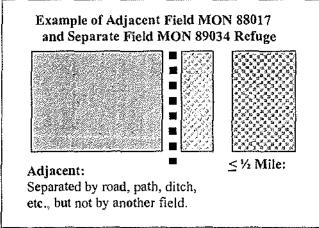
1

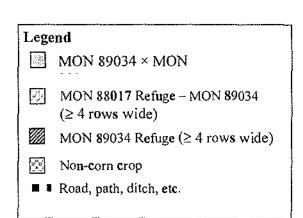




MON 89034 × MON 88017: Separate refuge placement and configuration options for MON 88017 and MON 89034







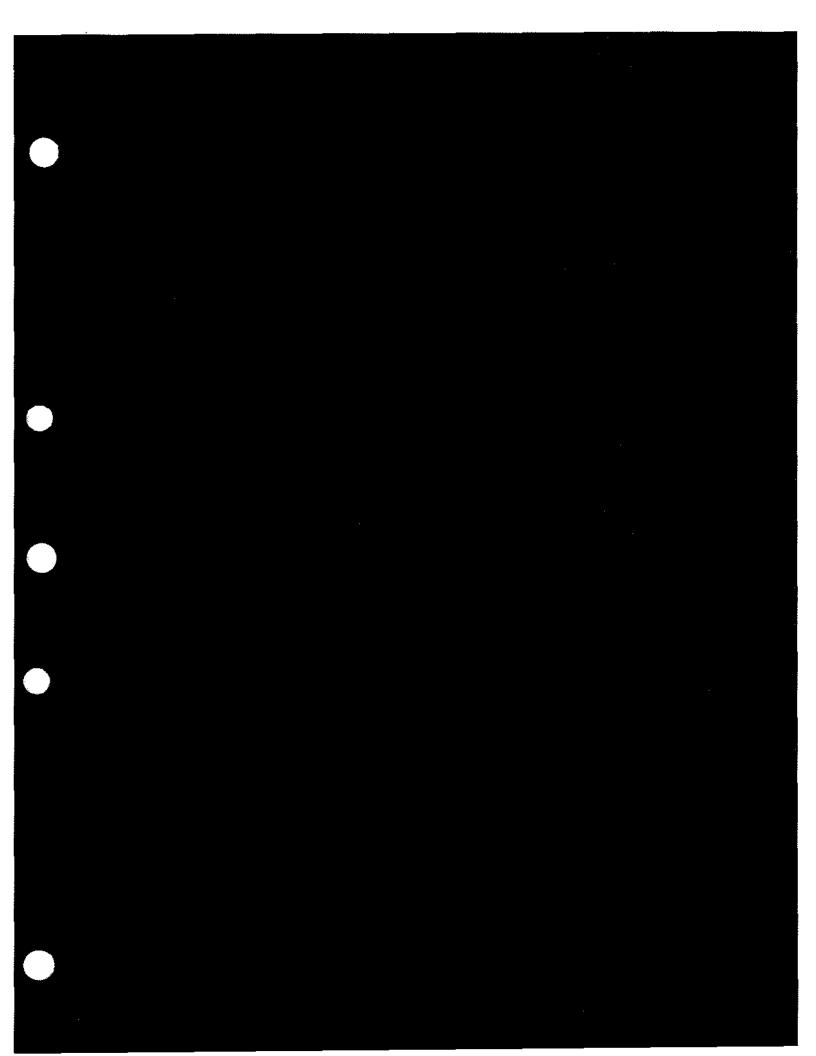
CORN INSECTS CONTROLLED OR SUPPRESSED

MON 89034 field corn, popcorn, and sweet corn produce the *Bt* proteins, Cry1A.105, Cry2Ab2, and Cry3Bb1, that control or suppress the following lepidopteran and coleopteran insects:

European corn borer (Ostrinia nubilalis)
Corn earworm (Helicoverpa zea)
Fall armyworm (Spodoptera frugiperda)
Southwestern corn borer (Diatrea grandiosella)
Southern cornstalk borer (Diatraea crambidoides)
Sugarcane borer (Diatrea saccharalis)
Western corn rootworm (Diabrotica virgifera virgifera)
Northern corn rootworm (Diabrotica barberi)
Mexican corn rootworm (Diabrotica virgifera zeae)

MON 89034 × MON 88017 is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. Patents: 38-21(52905); 38-21(53618); 4,940,835; 5,164,316; 5,188,642; 5,196,525; 5,322,938; 5,359,142; 5,633,435; 5,641,876; 5,717,084; 5,728,925; 5,804,425; and 6,501,009.

(231)



Title

Administrative Materials for the Submission of Supplemental Information to Address EPA Questions Regarding Applications 524-LTL and 524-LTA to Register Insect-protected Corn MON 89034 and MON 89034 x MON 88017 (MRID 46951400 and 46951300)

CONFIDENTIAL ATTACHMENT

Author

Natalia N. Bogdanova, D.V.M.

Registrant Submission Date

March 9, 2007

Registrant Submitting

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

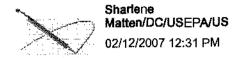
Registrant Document No.

04-CR-172E-2

Volume 1 of 3

233

EPA Registration File No. 524-575 (Vol. 1).
Page is not included in this copy.
Pages 234 through 236 are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
X The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Enforcement sensitive information.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.
* The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



- To "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>
- cc "BOGDANOVA, NATALIA N [AG/1000]"

 <natalia.n.bogdanova@monsanto.com>, Alan
 Reynolds/DC/USEPA/US@EPA, "REDING, H KEITH

bcc

Subject Re: Notes from the phone conversation on February 6, 2007

Natalia -- Thank you for the phone conversation. I have a few corrections to the notes you have provided. See my comments in **gree**n below. **Thanks. SRM** -----"BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com> wrote:

To: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com>, Sharlene Matten/DC/USEPA/US@EPA, Alan Reynolds/DC/USEPA/US@EPA From: "BOGDANOVA, NATALIA N [AG/1000]" <natalia.n.bogdanova@monsanto.com> Date: 02/08/2007 03:11PM

cc: "REDING, H KEITH [AG/1000]" <h.keith.reding@monsanto.com>, "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>, "LAHMAN, LINDA K [AG/1000]" linda.k.lahman@monsanto.com>, Susanne Cerrelli/DC/USEPA/US@EPA, Mike Mendelsohn/DC/USEPA/US@EPA

Subject: Notes from the phone conversation on February 6, 2007

Sharlene,

Thank you for a very informative conversation yesterday. This message is to summarize the key points of the discussion to make sure we are in agreement.

In order to maintain sweet corn in Monsanto's application to register MON 89034 and MON 89034 x MON 88017 the following plan was proposed:

Sweet corn

- In order to obtain registration for sweet and popcorn a limited dataset should be provided.
- Leaf expression data for MON 89034 that will be provided by Monsanto should be sufficient to retain sweet corn in the application. EPA agrees we can collect expression data from the leaf of flowering MON 89034 sweet corn currently being grown in Hawaii. The leaf tissue is currently being harvested and the data is expected to be submitted to EPA in March 2007.
- Limited efficacy data (leaf disk insect bioassay using ECB and FAW) will be also collected and provided to the Agency within similar timeframe.
- If necessary, FAW and ECB efficacy can be confirmed in field efficacy trials at a single location in 2007-08.

Comments on bullets 2-4:

I didn't say just leaf expression data were adequate. What I said was that a leaf disc bioassay would be the first step one would need to support the sweet corn use. I then said that Monsanto would need both field efficacy data and field expression data and that

this could be done using the MON 89034 sweet corn currently being grown in Hawaii and such data would be submitted in Fall 2007. One would have to explain how these data would be representative of other mainland growing areas for sweet corn. In addition to leaf expression, one needs pollen expression, stalk expression, and ear expression for pests such as corn earworm, fall armyworm, and European corn borer (although I would expect this pest to be of lesser importance for sweet corn given where it is grown in the U.S.) at the appropriate plant developmental stages.

The timing of actions for sweet corn should not affect field corn registration PRIA date unless that data is submitted later that January 2008. Sharlene indicated that how the data submitted in March 2007 and later in 2007 to support the sweet corn use (insect resistance management issues) would affect the PRIA date needs to be discussed with Susanne Cerrelli and Mike Mendelsohn as well as any administrative or regulatory question.

Popcorn

ì

- Popcorn varieties of MON 89034 have not been developed yet.
- Both field efficacy and expression data would need to be submitted at some future date to address insect resistance management should MON 89034 be registered for popcorn use.
- Monsanto prefers that popcorn be retained in the registration request but as a condition of the registration, expression and efficacy data must be provided before MON 89034 can be commercialized in popcorn. Sharlene pointed out that without any data to support the popcorn use that this would be unlikely. She indicated that this issue should be discussed further with the RALs, Susanne Cerrelli and Mike Mendelsohn.

Please, let me know if we understood each other correctly. Thank you very much for your time and attention to MON 89034.

Best regards,

Nat**a**lia

----Original Message-----

From: BOGOANOVA, NATALIA N [AG/1000]
Sent: Tuesday, February 06, 2007 11:19 AM

To: 'matten.sharlene@epa.gov'

Cc: REDING, H KEITH [AG/1000]; SCHNEIDER, RUSSELL P [AG/1920]

Subject: Information for today's discussion

Sharlene,

Here is the information we would like to discuss in the call this afternoon.

EPA Discussion Points for MON 89034 Sweet Corn

In a January 17, 2007 letter to Monsanto, EPA requested expression data on sweet corn and popcorn to perform an IRM assessment.

- We can provide expression data on MON 89034 sweet corn by mid-March 2007. We currently have MON 89034 sweet corn growing in Hawaii. The plants are at the flowering stage. We plan to take leaf samples from up to 10 plants and determine the dry weight expression of Cry1A.105 and Cry2Ab2.
- Field corn, popcorn and sweet corn all belong to the taxonomic group

 Zea mays subsp. mays; therefore, we expected that the expression level for sweet



corn and popcom to be in the range seen for field corn.

- The proposed IRM plan for sweet corn requires no structured refuge but rather destruction of the stalks after harvest, before the larvae can mature. Therefore, the expression level of the proteins should have no impact on the overall IRM plan.
- MON 89034 has not been bred into popcorn at this time. However, we would like popcorn included on the label to allow for future use in popcorn.

Look forward to talk to you.

Natalia

Natalia N. Bagdanava, D.V.M. Regulatory Affairs Manager Monsanta Company 800 North Lindbergh Blvd., 5t. Louis, MO 63167

Tel. (314) 694-3143 FAX (314) 694-3080

This e-malt message may contain privileged and/or confidential information, and is intended to be received only by persons entitled to receive such information. If you have received this e-mail in error, please notify the sender immediately. Please delete it and all attachments from any servers, hard drives or any other media. Other use of this e-mail by you is strictly prohibited.

Alt e-mails and attachments sent and received are subject to monitoring, reading and archivat by Monsanto. The recipient of this e-mail is solely responsible for checking for the presence of "Viruses" or other "Malware". Monsanto accepts no tiability for any damage caused by any such code transmitted by or accompanying this e-mail or any attachment.

BPPD WORK ASSIGNMENT #07-016 ORNL IAG #89939652-01 Date Mailed: Jan. 11, 2007

PRIA Due Date: April 01, 2007

- Oak Ridge National Laboratory (ORNL) shall independently review the studies identified below and prepare for each study a Data Evaluation Record (DER). In addition to its scientific expertise, the ORNL shall use the appropriate OPP Test Guidelines, science policy documents and other guidelines and materials provided to ORNL for the purpose of training, orientation and guidance concerning the preparation of DERs under the IAG.
- 2. For technical/scientific questions that cannot be resolved by the ORNL without input from BPPD science staff, the ORNL shall contact: Patty Moe

3. MRIDs and Studies for this work assignment are as follows Susanne Cerrelli 703-308-8077

EPA Reg. No.

524-LTA; LTL;

Product Name:

MON 89034

Ingredients:

Bacillus th

Company:

Monsanto Com

Company: Barcode	DP	MRID#	Study Type	Est. Hours
335189		469513-06	Insect Resistance	30
335208		469514-15,30)	
335188		46953-04-05	Non-target organisms	
Total Est. Ho	urs			30

3 Transmittal dates for the First Draft of the DERs to BPPD shall conform generally to the AWorking Days@ specified in ORNL Proposal #1834-S511-A1. The Work Assignment Manager will review the proposed Transmittal and Due Dates and negotiate a mutually acceptable schedule for EPA and ORNL for delivering the first draft of the DERs. For research reports that do not include estimated hours, please notify the Work Assignment Manager with and questions or hour estimates.

BPPD WORK ASSIGNMENT #07-016 ORNL IAG #89939652-01 Date Mailed: Jan. 11, 2007

PRIA Due Date: April 01, 2007

- Oak Ridge National Laboratory (ORNL) shall independently review the studies identified below and prepare for each study a Data Evaluation Record (DER). In addition to its scientific expertise, the ORNL shall use the appropriate OPP Test Guidelines, science policy documents and other guidelines and materials provided to ORNL for the purpose of training, orientation and guidance concerning the preparation of DERs under the IAG.
- 2. For technical/scientific questions that cannot be resolved by the ORNL without input from BPPD science staff, the ORNL shall contact: Patty Moe

3. MRIDs and Studies for this work assignment are as follows Susanne Cerrelli 703-308-8077

EPA Reg. No.

524-LTA; LTL:

Product Name:

MON 89034

Ingredients:

Bacillus th

Company:

Monsanto Com

Company: Barcode	DP	MRID#	Study Type	Est. Hours
335189		469513-06	Insect Resistance	30
335208		469514-15,30		
335188		46953-04-05	Non-target organisms	
Total Est. Ho	urs			30

Transmittal dates for the First Draft of the DERs to BPPD shall conform generally to the AWorking Days@ specified in ORNL Proposal #1834-S511-A1. The Work Assignment Manager will review the proposed Transmittal and Due Dates and negotiate a mutually acceptable schedule for EPA and ORNL for delivering the first draft of the DERs. For research reports that do not include estimated hours, please notify the Work Assignment Manager with and questions or hour estimates.

OAK RIDGE NATIONAL LABORATORY

MANAGED BY UT-BATTELLE FOR THE DEPARTMENT OF ENERGY

April 2, 2007

CUSTODY RECEIPT FOR FIFRA CONFIDENTIAL BUSINESS INFORMATION

TO: Pamela Landis Biopesticides and Pollution Prevention Division Office of Pesticide Programs U.S. Environmental Protection Agency One Potomac Yard 2777 South Crystal Drive Arlington, VA 22202

FROM: R. H. Ross, Group Leader Toxicology and Hazard Assessment Group 1060 Commerce Park Oak Ridge, Tennessee 37830 (865) 574-7797 FAX (865) 574-5353 email rossrh@ornl.gov

INSTRUCTIONS:

Original of this receipt to be signed by recipient and returned to sender.
 Duplicate of this receipt to be retained by recipient.

						Hours	
TASK No.	MRID No.	Chemical/Agent	WAM	Material Sent	Status	Est.	Actual
07-016	46951306 46951430 46951304 46951415 46951305	MON 89034 x MON 88017	Landis	5 DERs 5 Study reports 1 Custody sheet 1 CD	Draft	50	75

I have personally received from the sender material, enclosures, and attachments as identified above. I assume full responsibility for the safe handling storage and transmittal of this material in accordance with existing FIFRA Confidential Business Information regulation

DATE RECEIVED:

SIGNATURE



Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143

MONSANTO COMPANY
800 NORTH LINDBERGH 8LVO
St. Louis, Missouri 63167
http://www.monsanto.com

J. SUBMISSIONS

February 5, 2007

Document Processing Desk Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency One Potomac Yard 2777 S. Crystal Drive Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly

Subject: Memorandum of Understanding; EPA Petition Numbers 6F7142 and 6F7143;

EPA File Symbols: 524-LTA and 524-LTL

Dear Dr. Reilly,

I would like to thank you and the other members of your team for meeting with Monsanto on January 25, 2007 to address reviewer's questions regarding the IRM plan proposed for Monsanto's second generation lepidopteran-protected corn product MON 89034 (EPA File Symbol 524-LTL).

The summary and conclusions from our conversation are provided below. Please add to or revise them if your understanding of the meeting differs.

EPA Participants:

Sheryl Reilly, Sharlene Matten, Mike Mendelsohn, Tess Milofski, Alan Reynolds, Susame Cerelli, Particia Moe

Monsanto Company Participants:

Russell Schneider, Linda Lahman, Graham Head, Natalia Bogdanova

The discussion focused around the January 17, 2007 letter from EPA that outlined general questions and requests for information, and specific questions related to the proposed IRM plan for MON 89034. Graham Head presented an outline of the IRM plan and discussed the underlying data. Questions listed below (in italics) are quoted from the letter of January 17, 2007.

243

Dr. S. Reilly February 5, 2007

General questions:

response letter.

1. The insect resistance management (IRM) package for MON 89034 x MON 88017 is deficient. There is no bridging rationale provided that links the dose and efficacy of the stacked product to that of each single gene product for each target pest as justification for the proposed IRM plan for the stacked product.

Monsanto will provide a bridging rationale that includes expression and efficacy data against target pests by comparing single and combined trait products.

2. Expression data are necessary for popcorn and sweet corn in order to perform the IRM assessment.

For the IRM assessment of MON 89034 sweet corn and popcorn, the Agency requested limited expression and efficacy data to bridge with data obtained for field corp. Information regarding the similarity of sweet com to field corn and relevance to IRM would not be sufficient for the existing EPA framework. Information sweet com can be applied to popcorn! Monsanto will follow up on the request in a

3. The tolerance pelitions requests that 40 CFR Part 180 be amended to remove time limitation for the temporary exemptions from the requirement of a tolerance. These need to be modified so that you request to amend 40 CFR Part 174.453 and 174.454 to make arphi Aarphithem permanent exemptions from the requirement of a tolerance. Temporary tolerance exemptions not only have time limitations, but are linked to specific experimental use permits.

As directed by EPA Monsanto will re-submit petitions to amend temporary tolerances for the Cry1A.105 and Cry2Ab2 proteins with requests for permanent tolerances to support the registration request for MON 89034. In addition, Monsanto will extend the request to include all crops and commodities based on confirmation from EPA. This action has no impact on timelines for MON 89034.

4. IRM-specific questions:

- a. What are the relative contributions of each toxin (i.e., dose of each toxin and selection)? Explain "dose" studies and your assumptions about dominance and inheritance of resistance.
- b. How is Roush's model used for predicting resistance (relative contribution of each toxin) to ECB? What are the assumptions?
- c. What information relative to each toxin, is being fitted to the Monsanto revised bollworm model?

Graham Head addressed the above questions in the presentation. Monsanto will provide additional clarification on the methods used to assess the level of control (dose) conferred by each of the Cry1A.105 and Cry2Ab2 components in MON 89034, and how these data

Dr. S. Reilly February 5, 2007

are incorporated into mathematical models for the different target pests. However, no additional data should be necessary. Monsanto will also provide the PowerPoint presentation that was used at the meeting.

The following topics were also discussed:

- Benefits data and content of a Public Interest Document (PID) that Monsanto provides to EPA for each product were discussed. Sharlene Matten provided a handout with guidance on information the Agency would need, including the activity of our product on fall armyworm. Monsanto plans on submitting MON 89034 and MON 89034 x MON 88017 PIDs later this year.
- The Agency indicated that it was helpful to the reviewer to have relevant background
 data such as expression in the IRM volume. Monsanto pointed out that Volume 2 of
 the submission contains a summary of the submission and can be used as reference
 for each study if necessary.

Based on this conversation, Monsanto will provide responses to the questions posed in the EPA letter of January 17 within the next two weeks.

We would appreciate an affirmation of EPA's agreement with these notes. If you would like to discuss this memorandum of understanding, please contact Dr. Russ Schneider at (202) 383-2866 or me at (314) 694-3143.

Sincerely,

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

Natah N. Bylauna

cc: Russ Schneider/Monsanto Monsanto Regulatory Files





EPA/Monsanto meeting January 25, 2007

The Second Generation Lepidopteran-protected Corn Product MON 89034: IRM Considerations

(Vector PV-ZMIR245)

Dr. Natalia Bogdanova Dr. Graham Head

Monsanto Company



Agenda

- Product Overview and Status
- IRM considerations for MON 89034
- Discussion

Monsanto Company



Second Generation Lepidopteranprotected Corn: Product Description

MON 89034

- Vector PV-ZMIR245
- Active Ingredients Cry2Ab2 and Cry1A.105
- Inert Ingredient None

MON 89034 x MON 88017

- Produced by conventional breeding of MON 89034 and MON 88017
- Vectors PV-ZMIR245 and PV-ZMIR39
- Active Ingredients Cry2Ab2 and Cry1A.105, and Cry3Bb1
- Inert Ingredient -



Product Concept

✓ Increased spectrum of activity against lepidopteran insect pests compared to MON 810

Ostrinia – ECB

Diatrea - SWCB, SCB

Additional activity:

Spodoptera - FAW

Helicoverpa - CEW

- ✓ IRM benefit: produce two Bt proteins, Cry1A.105 and Cry2Ab2
- ✓ In addition:
 - Combination with MON 88017 offers CRW protection and herbicide tolerance



Current Status

- ✓ Temporary tolerance exemptions for Cry1A.105 and Cry2Ab2 protein granted in June 2006
- ✓ Field testing ongoing under an EUP (524-EUP-97)
- ✓ Applications to register MON 89034 and MON 89034 x MON 88017 submitted in September 2006
- Petitions to amend temporary tolerance exemptions for Cry1A.105 and Cry2Ab2 to remove time limitations submitted in November 2006

Management for MON 89034 Insect Resistance

Monsanto Company



Overview

- ☐ The dual effective dose concept
- MON 89034 as a dual effective dose product
 - Low likelihood of cross-resistance between Cry1A.105 and Cry2Ab2
 - High level of control of key target pests
- IRM considerations



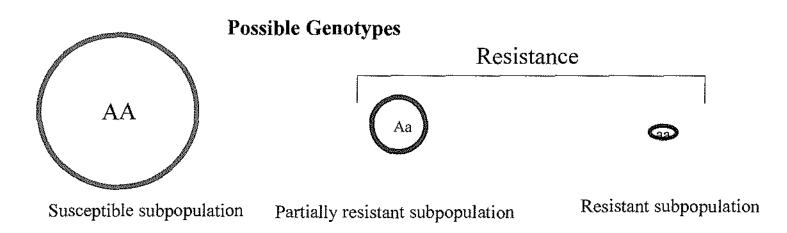
Dual Effective Dose Concept

- For a product with two Bt proteins, the IRM benefit is greatest when Bts are not cross-resistant and each gives at least 95% control of target pests = Dual Effective Dose
 - Value is considerable if at least one protein gives >95% control
- Dual Effective Dose (DED) against key target pests:
 - Demonstrate high level of control by each protein
 - Demonstrate low probability of cross-resistance



With one Bt protein:

Eliminate most of the resistant alleles from the population using a high dose



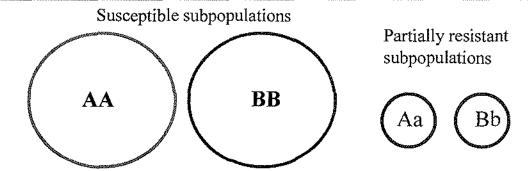
The most effective way to eliminate resistant alleles is killing partially resistant insects because these Aa insects are much more common than the fully resistant aa insects.

High dose is the concentration needed to kill the susceptible and partially resistant insects.

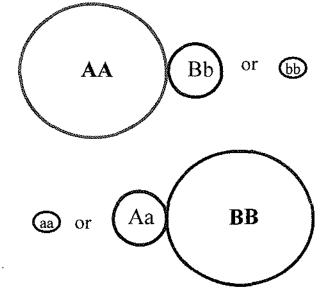


With two Bt proteins:

Eliminate most of the resistant alleles from the population using an effective dose of each protein



We assume that the two resistant loci assort independently.

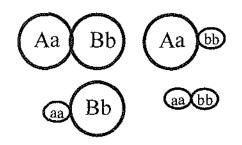


IRM goal is an effective dose of both proteins to kill insects susceptible to either protein. This is because the insects we need to control in this case are those resistant or partly resistant to one protein but susceptible to the other protein (AAbb, AABb, AaBB and aaBB).

Other resistant phenotypes are rarer (AaBb, Aabb, aaBb and aabb) and are less important.

Resistant subpopulations

(bb)





With two Bt proteins:

(assume allele freq = 0.002)

	AB	Ab	аВ	ab
AB	AABB 99.2	AAB b 0.20	AbBB 0.20	AaBb 0.0004
Ab	AABb 0.20	AAbb 0.0098	AaBb 0.0004	Aabb 0.0000008
аВ	AaBB 0.20	AaBb 0.0004	aaBB 0.0004	aaBb 0.0000008
ab	AaBb 0.0004	Aabb 0.0000008	aaBb 0.0000008	Aabb 0.0000000016

Compared with one protein, where Aa = 0.4% and aa = 0.0004%

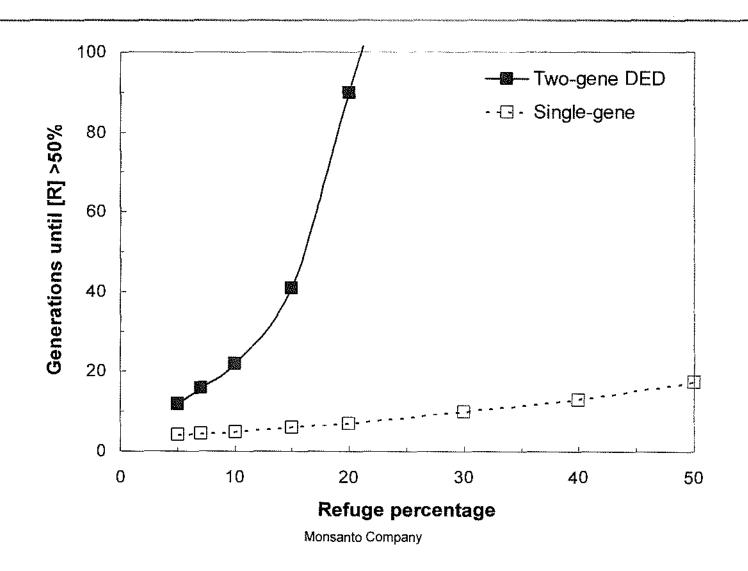


Dual Effective Dose Criteria

- Modeling by Roush based on diamondback moth (DBM) genetics
 - Resistance is partially recessive (heterozygotes show some resistance)
- Little or no cross-resistance and 95% control of susceptible insects is desired
 - If resistance is more recessive, then Dual Effective Dose products are even more durable
- ☐ This modeling is the basis for the IRM decisions made for Bt cotton in Australia



Durability of DED with 5% Refuge ≥ Durability of Single-Gene with 20% Refuge





Low Likelihood of Cross-resistance Between Cry1A.105 and Cry2Ab2

(comparable to Bollgard II case)

- Substantial sequence and structural differences suggest differences in mode of action
- Differences in binding receptors and kinetics of binding
- No significant cross-resistance of Cry2Ab2-resistant Helicoverpa armigera to Cry1A.105



No Significant Impact of Prior Use of Cry1Ab-expressing Corn on MON 89034

- □ Differences in binding characteristics of Cry1Ab and Cry1A.105
- No significant cross-resistance of Cry1Abresistant ECB to Cry1A.105
- No evidence of increased Cry1Abresistant allele frequencies in US populations of ECB, SWCB and CEW over the past decade



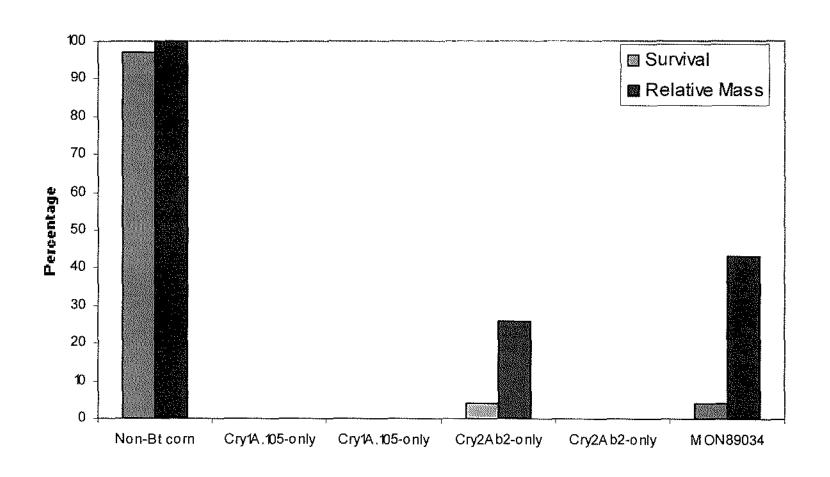
Level of Control by MON 89034: in vitro protein assays

	MIC ₉₀	(ppm)
Species	Cry1A.105	Cry2Ab2
ECB	0.36	3.40
SWCB	5.40	28.4
CEW	10.7	52.9

Compare with MON 89034 expression levels in leaf of 20-30 ppm for Cry1A.105 and Cry2Ab2

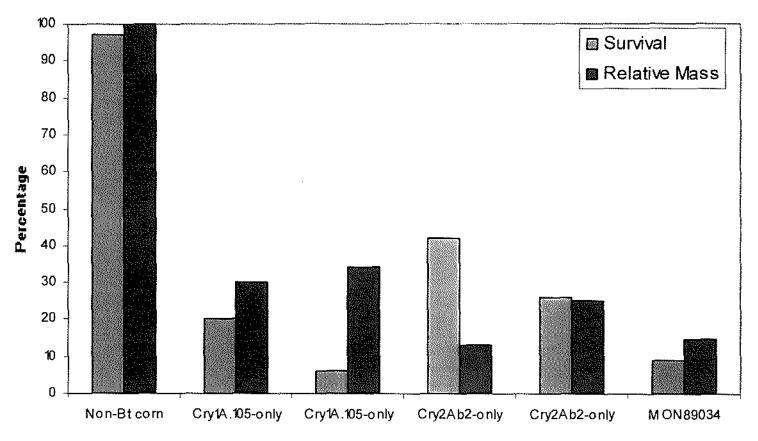


ECB Control by MON 89034: in planta (leaf disk) assays





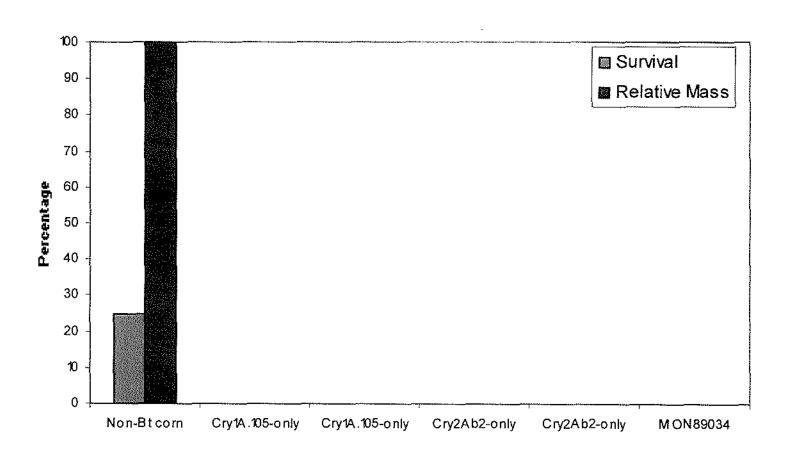
SWCB Control by MON 89034: in planta (leaf disk) assays



Note the small size of surviving larvae.



CEW Control by MON 89034: in planta (leaf disk) assays





Level of Control by MON 89034: Overall Conclusions

- ECB: DED (>>95% control from each protein) level of control
- □ SWCB: approximately 95% control (probably greater) for Cry1A.105 and approx. 90% control for Cry2Ab2
- CEW: similar pattern to SWCB



Modeling MON 89034 Durability: Corn Belt

- Conservatively fitted by the modeling of Roush that assumed partially recessive resistance (the DBM model)
- □ ECB: level of control by each protein is so high that a refuge <<5% could still provide durability equivalent to current single-gene products
- □ SWCB/CEW: level of control by each protein is approximately 95% (and CEW over-wintering is very limited in this region) so a 5% refuge supportable



Modeling MON 89034 Durability: Cotton-growing Region

- Used modeling developed for Natural Refuge initiative to model CEW in the southern US
- Assumed that Natural Refuge is granted for Bollgard II cotton and MON 89034 is fully cross-resistance to Bollgard II
- □ 20% refuge gives 25 yr durability



IRM Plan for MON 89034

- 5% refuge size proposed for the Corn Belt based on the two independent, highly effective modes of action of Cry1A.105 and Cry2Ab2
- 20% refuge size proposed for cotton-growing areas – complements CRW
- □ IRM elements otherwise comparable to current products
- □ Risk reduced relative to single-gene products with current refuge sizes



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



November 17, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-371189

EPA File Symbol or Registration Number: 524-LTL

Product Name: MON 89034 EPA Receipt Date: 29-Sep-2006 EPA Company Number: 524

Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER MONSANTO CO MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee -- Revised

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as B81 has been reclassified as Action Code: B81.2

PIP; REGISTER NEW AI; TEMP. TOLERANCE/EXEMPTION EXISTS SAP REQUIRED; INCREASED PRIA FEE: Two AIs;

The fee for this aciton us \$630,000. Payment in the amount of \$315,000 has been received. Please remit additional payment in the amount of \$315,000.

By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251

(269)

By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277

Pittsburgh, PA 15251-6277 Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency 1200 Pennsylvania Ave NW Washington, DC 20460 By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202

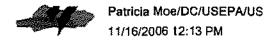


A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Front End Processing Staff

Information Technology & Resources Management Division



- To John Jamula/DC/USEPA/US
- cc Sheryl Reilly/DC/USEPA/US, Robert Torla/DC/USEPA/US@EPA

bcc

Subject 524-LTL revised billing

JJ: I am sorry, but I have a correction to make on a coding/billing for a PIP.

524-LTL was coded as a B81 Mon 89034* should have been charged for 2 new ais (that is, B81 x2).

There is also the a stacked product (524-LTA) which came in at the same time. this registrations is a child and will not be charged (per our policies regarding parent-children).

The registrant has already paid for the one B81.

Please let me know if you need any additional information. Patty

* This is a chimeric Cry 1A.105 x 2Ab2 and is the first time each has been registered in corn

Patricia Moe Team Leader Microbial Pesticides Branch Biopesticides and Pollution Prevention Division Office of Pesticide Programs/ U.S. EPA phone: 703-305-0744

FAX: 703-308-7026



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



December 5, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-371189

EPA File Symbol or Registration Number: 524-LTL

Product Name: MON 89034 EPA Receipt Date: 29-Sep-2006 EPA Company Number: 524

Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER MONSANTO CO MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee -- Revised

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B81.2

PIP;REGISTER NEW AI;TEMP. TOLERANCE/EXEMPTION EXISTS SAP REQUIRED;INCREASED PRIA FEE: Two AIs;

The fee associated with this action is \$420,000. Payment in the amount of \$315,000 has been received. Please remit additional payment in the amount of \$105,000 to:

By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251 By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277 Pittsburgh, PA 15251-6277

Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER) Office of Pesticide Programs (7504C) U.S. Environmental Protection Agency 1200 Pennsylvania Ave NW Washington, DC 20460 By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall #2
1801 S. Bell St.
Arlington, VA 22202



A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Janet Andersen/DC/USEPA/US 12/04/2006 03:56 PM

To John Jamula/DC/USEPA/US@EPA

Diana Hudson/DC/USEPA/US@EPA, Patricia

bcc

Subject Re: Renegotiation on PRIA fee⊞

That will be great. Thanks. John Jamula/DC/USEPA/US

John Jamula/DC/USEPA/US t2/04/2006 03:31 PM

To Janet Andersen/DC/USEPA/US@EPA

Diana Hudson/DC/USEPA/US@EPA, Patricia

cc Moe/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject Re: Renegotiation on PRIA fee

Janet,

Because there is only one decision record which can accommodate one action code here is what I propose to do.

Monsanto was originally billed for \$630,000 (B81.2 two new ai's). They paid \$315,000. I can adjust the original bill to \$420,000 by applying an administrative discount and send an invoice for the remaining \$105,000. Would that work for you?

<ال

Janet Andersen/DC/USEPA/US

Janet Andersen/DC/USEPA/US 12/04/2006 03:16 PM

To John Jamula/DC/USEPA/US@EPA

Patricia Moe/DC/USEPA/US, Diana cc Hudson/DC/USEPA/US@EPA, Sheryl Reilly/DC/USEPA/US@EPA

Subject Renegotiation on PRIA fee

Invoice D 371189 has a B81 and a B81.2 with it. B81 stays as is at \$315,000. But B81.2 should go down to \$105,000 based on the work we have already done on the pesticidal protein. Monsanto is ready to cut the check with the new invoice. Thanks.

216

Date

Checklist for Data Packages/Administ e Material (524-C7C

Name of active ingredient

) AL Sasume (, + Mile Mandelphy

MON 89034

	y		- nm		Comments
Admin Materiats	Stgned	Date	present	Absent	
Form 8570-1	40	4/18/06	-		4 4 4
CSF - Comdittely filled out & original signature	AIN	ahan	· ·		0105 - Nothing Was Chenting CSEC
Method of Supdort .	V	7,,-,,-			
Label	dQ/1				swort-
Physical address of manufacturer on label	w				
Data Matrix - Two/one for jacket; one for FDIA	10194	9/18/10/5	-		
Transmittal letters	i chain	1,-5			
Petition/amended detition if food tolerance or exemption/a	menden	1			
food tolerance or exemption	<u> </u>				
FR template if food tolerance or exemption/amended food	Las		1		in home we be for sell don life
tolerance or exemption	720				The west of the office of the
Data Compensation forms, if required	<u> </u>		<u> </u>		<u> </u>
Minutes on data requirements (pre-registration meeting)					
Active ingredient # ti.e. Chemical PC code)	<u> </u>				
Jacket from EPA identifying Symbol	\V/_)			SY U - C - T/
Background Experimental Use Permit Information, if applica	bie /				
			<u> </u>		
		1	lŧ :		

Starlene week_

John need-?>





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

October 10, 2006

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-371189

EPA File Symbol or Registration Number: 524-LTL

Product Name: MON 89034 EPA Receipt Date: 29-Sep-2006 EPA Company Number: 524

Company Name: MONSANTO COMPANY

RUSSELL P. SCHNEIDER MONSANTO CO MONSANTO COMPANY 1300 I STREET, NW, SUITE 450 EAST WASHINGTON, DC 20005

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B81

PIP; REGISTER NEW AI; TEMP. TOLERANCE/EXEMPTION EXISTS SAP REQUIRED;

Please remit payment in the amount of: \$ 315,000 to:

By USPS:

USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251



By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277

Pittsburgh, PA 15251-6277 Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER) Office of Pesticide Programs (7504P) U.S. Environmental Protection Agency 1200 Pennsylvania Ave NW Washington, DC 20460 By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

- Andrews

Sincerely

Front End Processing Staff

Information Technology & Resources Management Division

NEW APPLICATIONS

DATE: 10/3/06
FILE NUMBER: 534-474
FEP (OPPIN ENTRY): 10/3/06pem (Initial & date)
FILE ROOM: Left 10/11/05 (Initial & date)
SIG: <u>KG 10/12/2006</u> (Initial & date)
FILE ROOM: Jw 10-13-06 (Initial & date)
ASSIGN TO PM 92

Submission for

Biopesticides and Pollution Prevention Division (BPPD)

MRID# 469514

Deliver to Patricia Moe after coding





Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314)-694-3143 MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
http://www.monsanto.com

September 28, 2006

Document Processing Desk (EUP)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Application for the registration of the plant-incorporated protectant Bacillus thuringiensis

Cry1A.105 and Cry2Ab2 proteins produced in MON 89034

Dear Dr. Reilly:

Please find enclosed an application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in the comproduct MON 89034. MON 89034 is a second-generation product that produces the Cry1A.105 and Cry2Ab2 proteins, which together control a wider spectrum of lepidopteran pests and offer an enhanced insect resistance management (IRM) tool compared to the current lepidopteran-protected corn product MON 810.

EPA established temporary exemptions from the requirement of a tolerance for the Cry1A.105 and Cry2Ab2 proteins and the genetic material for their production in corn (40 CFR §174.453 and 40 CFR §174.454, respectively). The results of the safety assessment demonstrated that the Cry1A.105 and Cry2Ab2 proteins as produced in MON 89034 will not pose any significant risk to human health or to the environment.

This application includes the following documents that, for purposes of placement in the Public Docket, have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf files are included on a CD-ROM for placing documents classified as 'A' on the Edocket. The redacted version of the Administrative volume (.pdf file) for the Edocket excludes the data matrix (agency internal use copy) and confidential attachment. Complete description of this submission by category is provided in the attachment to this letter.



Dr. S. Reilly Sept 28, 2006 Page 2 of 5

It is Monsanto's understanding that the following fee category and amount is appropriate based on the June 2, 2005 Federal Register notice for Pesticide fees and Decision Times:

- Fee category B81: Register new AI, temporary tolerance or exemption exists, SAP required;
- Fee Category Amount: \$315,000

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

cc;

Natalia N. Bogdanova, D.V.M.

Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto Monsanto Regulatory Files

ATTACHMENT

Volume	Category	Document	Hard Copy	.pdf file for Edocket
N/A	A	Cover letter	√	√ √
N/A	A	Transmittal document		1
1	A	Administrative volume	√	
1	С	Confidential statement of formula	- √	
l	A	Administrative volume (redacted copy)		1
2	В	Human Health and Environmental		
		Assessment of the Plant-Incorporated		
		Protectant Bacillus thuringiensis		
		Cry1A.105 and Cry2Ab2 Proteins		
		Produced in Corn MON 89034.		
3	В	Molecular Analysis of Corn MON 89034.	4	
4	В	Assessment of the Cry1A.105 and		
·	-	Cry2Ab2 Protein Levels in Tissues of	•	
		Insect-Protected Corn MON 89034		
ĺ		Produced in 2005 U.S. Field Trials.		7
5	В	Characterization of the Cry2Ab2 Protein	V	
		Purified from the Com Grain of MON		
	İ	89034 and Comparison of the		****
		Physicochemical and Functional		İ
		Properties of the Plant-Produced and E .		
		coli-Produced Cry2Ab2 Proteins.		
6	В	Evaluation of the Functional Equivalence	√	
		of the Cry2Ab2 Protein Produced in E.		
		coli and Bt Against a Sensitive		
		Lepidopteran Species.		
7	В	An Acute Oral Toxicity Study in Mice with Cry2Ab2 Protein.	1	
8	В	Assessment of the in vitro Digestibility	1	
		of the Cry2Ab2 Protein in Simulated		
		Gastric Fluid.		
9	В	Assessment of the in vitro Digestibility	- √	
ĺ	ļ	of the Cry IA. 105 Protein in Simulated		
		Intestinal Fluid.		
10	В	Assessment of the in vitro Digestibility	Ą	
		of the Cry2Ab2 Protein in Simulated		
		Intestinal Fluid.		
11	В	Bioinformatics Evaluation of the	\checkmark	
		Cry1A.105 Protein Utilizing the AD6,		
		TOXINS, and ALLPEPTIDES		:
		Databases.		



Dr. S. Reilly Sept 28, 2006 Page 4 of 5

Volume	Category	Document	Hard	pdf file for
			Copy	Edocket
12	В	Bioinformatics Analysis of the Cry2Ab2	√ √	
		Protein Utilizing the AD6, TOXIN5, and		
		ALLPEPTIDES Databases.		
13	В	Comparison of Broiler Performance and	1	
		Carcass Parameters When Fed Diets		
		Containing MON 89034, Control or		
		Commercial Corn.		
14	В	Spectrum of Insecticidal Activity of	7	Ì
		Bacillus thuringiensis Cry1A.105		
		Protein.		
15	В	Spectrum of Insecticidal Activity of	√	
		Bacillus thuringiensis Cry2Ab2 Protein.		
16	В	Assessment of the Efficacy of	\checkmark	
		Lepidopteran-protected Com MON		f
		89034 and MON 89597 Against Major		
		Insect Pests in United States, Puerto Rico		
		and Argentina During 2003-2004		
		Seasons.		
17	В	Evaluation of Dietary Effects of	$\sqrt{}$	
		Lyophilized Leaf Tissue from Corn		
		MON 89034 in a Chronic Exposure		
		Study with		
		Collembola (Folsomia candida).		
18	В	Evaluation of Exposure to MON 89034	√	
7		With the Cladoceran Daphnia magna:		
ĺ		An Acute Static-renewal Test With Corn		
		Pollen.		
19	В	Evaluation of Potential Effects of	\checkmark	
		Exposure to Cry1A.105 Protein in an		
1		Acute Study with the Earthworm in an		
:		Artificial Soil Substrate.		
20	_ в	Evaluation of the Dietary Effect(s) of a	√	
}		Cry1A.105 Protein on Honeybee Larvae		
		(Apis mellifera L.).		
21	В	Evaluation of the Dietary Effect(s) of a	√	
		Cry1A.105 Protein on Adult Honeybees		тупель.
		(Apis mellifera L.).		

Dr. S. Reilly Sept 28, 2006 Page 5 of 5

Volume	Category	Document	Hard	.pdf file for
			Copy	Edocket
22	В	Evaluation of Potential Dietary Effects of	\checkmark	
		Cry1A.105 Protein on the Ladybird		
		Beetle, Coleomegilla maculata		
		(Coleoptera: Coccinellidae).	·····	
23	В	Evaluation of Potential Dietary Effects of	\checkmark	
		Cry2Ab2 Protein on the Ladybird Beetle,		
		Coleomegilla maculata (Coleoptera:		
		Coccinellidae).		
24	В	Evaluation of Potential Dietary Effects of	\checkmark	
		Cry1A, 105 Protein on Minute Pirate		
		Bugs, Orius insidiosus (Hemiptera:		77
		Anthocoridae).	· · · · · · · · · · · · · · · · · · ·	-
25	В	Evaluation of Potential Dietary Effects of	\checkmark	
		Cry2Ab2 Protein on Minute Pirate Bugs,		
		Orius insidiosus (Hemiptera:		
		Anthocoridae).	· · · · · · · · · · · · · · · · · · ·	
26	В	Evaluation of Potential Effects of	√	
		Exposure to Cry1A,105 Protein in an		
		Acute Study with the Parasitic Wasp,		
		Ichneumon promissorius (Hymenoptera:		
		Ichneumonidae).	····	
27	В	Evaluation of Potential Effects of	\checkmark	
		Exposure to Cry2Ab2 Protein in an		
		Acute Study with the Parasitic Wasp,		
		Ichneumon promissorius (Hymenoptera:		
	T.	Ichneumonidae).		
28	В	Evaluation of Potential Dietary Effects of MON 89034 with the Northern	٧	
	į	Bobwhite: an Eight-day Dietary Study		·
		with Corn Grain.		
29	В	Aerobic Soil Degradation of the Purified		
2.5	D I	Cry2Ab2 and Cry1A.105 Proteins.	¥	
30	В	Endangered Species Risk Assessment for	7	
]	D	Corn MON 89034.	٧	
31	В	Insect Resistance Management Plan for		
,	D.	Second Generation Lepidopteran-	٧	l
		Protected Corn, MON 89034.		
		110100100 COIII, 11101Y 07037.		



LIST OF SUBMITTED DOCUMENTS

Volume 1.	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3).
	MRID Number
Product Sun	ımary
Volume 2.	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.
	MRID Number
Product Cha	racterization
Volume 3.	Rice, J.F., B.J. Wolff, J.R, Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.
	MRID Number
Volume 4.	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.
	MRID Number 48951403



Administrative Materials

Protein Safety

Volume 5.	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>E. coli</i> -Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.
	MRID Number 46951404
Volume 6.	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E.Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.
	MRID Number 46951405
Volume 7.	Bonnette, K.L. 2006. An Acute Oral Toxicity Study in Mice with Cry2Ab2 Protein. Monsanto Study CRO-2005-049.
	MRID Number 46951406
⁄olume 8.	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.
	MRID Number
olume 9	Kapadia, S. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.
	MRID Number



Volume 10		oley. 2006. Assessment of the <i>in vitro</i> Digestibility of Simulated Intestinal Fluid. Monsanto Technical
	MRID Number	46951409
Volume 11.	Cry1A.105 Protein Util	Ivanovich. 2006. Bioinformatics Evaluation of the izing the AD6, TOXIN5, and ALLPEPTIDES Technical Report MSL-20351.
	MRID Number	46951410
Volume 12.	Cry2Ab2 Protein Utiliz	Ivanovich. 2006. Bioinformatics Analysis of the ing the AD6, TOXIN5, and ALLPEPTIDES echnical Report MSL-20307.
	MRID Number	46951411
Volume 13.	Parameters When Fed I	nparison of Broiler Performance and Carcass Diets Containing MON 89034, Control or Commercial 05-01-50-13, Amended Report.
	MRID Number	48951412
Insecticidal A	<u>Activity</u>	
Volume 14.		wn, and S.L. Levine. 2006. Spectrum of Insecticidal ingiensis CrylA.105 Protein. Monsanto Technical
	MRID Number	46951413

Volume 15.	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Monsanto Technical Report MSL-20229.
	MRID Number 46951414
Volume 16.	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaughn. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.
	MRID Number
Ecotoxicolog	<u>v Studies</u>
Volume 17.	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (<i>Folsomia candida</i>). Monsanto Technical Report MSL-20169.
	MRID Number46951416
Volume 18.	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran <i>Daphnia magna</i> : An acute static-renewal test with corn pollen. Monsanto Study WL-2005-011.
	MRID Number 46951417
Volume 19.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cryl A. 105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.
	MRID Number 46951418



Volume 20.	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (<i>Apis mellifera</i> L.). Monsanto Study CA-2005 071.
	MRID Number 48951419
Volume 21.	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (<i>Apis mellifera</i> L.). Monsanto Study CA-2005-072.
	MRID Number
Volume 22.	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.
	MRID Number 48951421
Volume 23.	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.
	MRID Number 48951422
Volume 24.	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.
	MRID Number 46951423

Volume 25.	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae Monsanto Technical Report MSL-20171.							
	MRID Number							
Volume 26.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20149.							
	MRID Number 46951425							
Volume 27.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.							
	MRID Number 46951426							
Volume 28.	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.							
	MRID Number 46951427							
Volume 29.	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.							
	MRID Number46951428							

Volume 30. Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.

MRID Number	46951429	
MKID Number	10001720	

Insect Resistance Management

Volume 31. Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06.

MRID Number	46951430	
MINTEN LAURINGE		_

Company Official: Workel W. Bydoccom 09/28/06

Natalia N. Bogđanova, Ď.V.M.

Regulatory Affairs Manager

(314) 694-3143

Company Name: Monsanto Company

Company Contact: Russell P. Schneider, Ph.D.

Director, Regulatory Affairs

(202) 383-2866



TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

REGULATORY ACTION IN SUPPORT OF WHICH THIS DOCUMENT IS SUBMITTED

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

EPA File 524 - XXX

TRANSMITTAL DATE

September 28, 2006

MONSANTO REFERENCE No.

06-CR-I72E-1



Page 1 of 8





VOLUME 1

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A,105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

EPA File 524 - XXX

AUTHOR

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

SUBMISSION DATE

September 28, 2006

SUBMITTING REGISTRANT

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

							3					
								2	3	ŝ	3	
							3			> 5	;	
							;		3			1
								3	*	۶	2	
,	7	à	,	3	÷					3		
3			>		÷							
>					;		3	3			3	
							3		þ			
÷	2		j	5	,		,			3	,	
		1			,							
			,	ŗ			3			3	2	
							,		2	3		
2	4	,	j				-	3	ż	3	2	
1	ż	1	1	_	,			-	-	-	-	
		ĺ,	,		,					ş		
,	٥	,	,	•						•		
								>	\$	3	>	
							3					
								÷	ź	3	3	
								3	3	3	3	
							\$		è	3		
								à.	ź			

MONSANTO REFERENCE No.

06-CR-172E-1

295)

Monsanio Company Page 1 of 36 06-CR-172E-1

The text below applies only to use of the data by the United States Environmental Protection Agency (U.S. EPA) in connection with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

STATEMENT OF DATA CONFIDENTIALITY CLAIM

No claim of data confidentiality is being made for information contained in this document on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C). However, a supplemental data confidentiality claim is being made for some information claimed herein. The applicable information has been removed to a confidential attachment.

"We submit this material to the United States Environmental Protection Agency specifically under requirements set forth in FIFRA as amended, and consent to use and disclosure of this material by the EPA strictly in accordance with FIFRA. By submitting this material to EPA in accordance with the method and format requirements contained in PR Notice 86-5, we reserve and do not waive any rights involving this material that are or can be claimed by the company notwithstanding this submission to the EPA."

COMPANY: Monsanto Company

COMPANY AGENT: Watch W. Bylann

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

DATE: September 28, 2006

296

GLP COMPLIANCE STATEMENT

The materials in this volume do not meet the requirements of the Good Laboratory Practice Standards, 40 CFR Part 160. This volume provides the administrative materials for the application to register the plant-incorporated protectant, Bacillus thuringiensis Cry1A.105 and Cry2Ab2 proteins and the genetic material (vector PV-ZMIR245) necessary for their production in MON 89034, and therefore were not developed in compliance with 40 CFR Part 160.

Date
[23][DE
Date
)

Study Director Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

Date

VOLUME 1

TABLE OF CONTENTS

Statement of	Data Confidentiality Claim	Page 22
GLP Complia	ance Statement	3
Table of Cont	tents	4
Abbreviations	s and Definitions	5
Section I.	Administrative Materials	7 8 9
Section II.	Summary of the Application	28
Section III.	Product Label	29
Section IV,	Product Analysis	32
Section V.	Residue Data	33
Section VI.	Nontarget Organism Data	34
Section VII.	Toxicology Data	35
Section VIII.	Efficacy Data	36

Page 4 of 36

ABBREVIATIONS AND DEFINITIONS

Bt	Bacillus thuringiensis
CBI	Confidential business information
CFR	U.S. Code of Federal Regulations
CSF	Confidential Statement of Formula
	A chimeric protein comprised of sequences from the naturally
	occurring Cry1Ab, Cry1F, and Cry1Ac proteins from Bacillus
Cry1A.105	thuringiensis
Cry2Ab2	A crystal protein derived from Bacillus thuringiensis subsp. kurstaki
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
IRM	Insect resistance management
MON 89034	A Monsanto corn product, and the subject of this application for registration, that produces the insecticidal <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 proteins
MRID	EPA master record identification number
NTO	Nontarget organism
PR Notice	EPA Pesticide Registration notice
	Deoxyribonucleic acid vector (genetic material) used in the
PV-ZMIR245	transformation of corn to produce MON 89034

Page 5 of 36

SECTION I

ADMINISTRATIVE MATERIALS

Application to Register (Form 8570-1)

Confidential Statement of Formula (Form 8570-4)

Certification with Respect to Citation of Data (Form 8570-34)

Data Matrix (Form 8570-35)

Page 6 of 36

Monsanto Company

(200

CONFIDENTIAL STATEMENT OF FORMULA

{CBI Cross Reference Number 1}

Page 8 of 36

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S. W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Do not send the completed form to this address.							
Certification with	Respect to Citation o	f Data					
Applicant's/Registrant's Name, Address, and Telephone Number:	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	EPA Registration Number / File Symbol:					
Monsanto Company, 800 N. Lindbergh Blvd., St. Louis,	MO 63167	524-XXX					
(314) 694-3143							
Active Ingredient(s) and/or representative test compound(s): Bacillus		Date:					
and Cry2Ab2 Proteins and the Genetic Material (Vector PV-Z) their Production in MON 89034 (OECD Unique Identifier: Mo		September 28, 2006					
General Use Pattern(s) (list all those claimed for this product using 40 0	CFR Part 158:	Product Name:					
Terrestrial field crop	······	MON 89034					
NOTE: If your product is a 100% repackaging of another purchased need to submit this form. You must submit the Formulator's Exemption							
I am responding to a Data-Call-in Notice, and have included w should be used for this purpose).	ith this form a list of companies	sent offers of compensation (the Data Matrix form					
Section I: METHOD OF DA	TA SUPPORT (Check	one method only)					
I am using the cite-all method of support, and have included w this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).	the selective m completed list of	selective method of support (or cite-all option under ethod), and have included with this form a of data requirements (the Data Matrix form must be					
Section II: GE	used). NERAL OFFER TO PA	· · ·					
[Required if using the cite-all method or when using the cite-all		······································					
hereby offer and agree to pay compensation, to other person		•					
	I: CERTIFICATION						
I certify that this application for registration, this form for reregis the application for registration, the form for registration, or the Data-Call method is indicated in Section 1, this application is supported by all data identical or substantially similar product, one or more of the ingredients under the data requirements in effect on the date of approval of this appoint similar composition and uses.	I-In response. In addition, if the a in the Agency's files that (1) o in this product; and (2) is a type	cite-all option or cite-all option under the selective oncern the properties or effects of this product or an e of data that would be required to be submitted					
I certify that for each exclusive use study cited in support of this obtained the written permission of the original data submitter to cite that		hat I am the original data submitter or that I have					
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) Io pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) Io commence negotiations to determine the amount and terms of compensation, if any, Io be paid for the use of the study.							
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should Ffail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.							
	2 3 3 3 13 13 2 2 2 2 2 2 2 2 2 2 2 2 2						
l certify that the statements I have made on this form and all knowingly false of misleading statement may be punishable by fine							
Signature	Date	Typed or Printed Maine and Tide					
Nortale M. Paplacione	September 28, 2006	Natalia N. Bogdariova Regulatory Affairs Manager					

EPA Form 8570-34 (9-97) Electronic and Paper Versions available. Submit only Paper version.

ATTACHMENT

Volume	Category	Document	Hard Copy	.pdf file for Edocket
N/A	A	Cover letter	V	7
N/A	A	Transmittal document	√ ·	\ \
1	A	Administrative volume	1	
l	С	Confidential statement of formula	1	
ì	A	Administrative volume (redacted copy)		1
2	В	Human Health and Environmental	V	
		Assessment of the Plant-Incorporated		1
		Protectant Bacillus thuringiensis		
		Cry1A.105 and Cry2Ab2 Proteins		
		Produced in Corn MON 89034.		
3	В	Molecular Analysis of Corn MON	√	
:		89034.		
4	В	Assessment of the Cry1A.105 and	1	
		Cry2Ab2 Protein Levels in Tissues of		
		Insect-Protected Corn MON 89034		
		Produced in 2005 U.S. Field Trials.		
5	В	Characterization of the Cry2Ab2 Protein	V	
		Purified from the Corn Grain of MON		
		89034 and Comparison of the		
		Physicochemical and Functional		
		Properties of the Plant-Produced and E.		
		coli-Produced Cry2Ab2 Proteins.		
6	В	Evaluation of the Functional Equivalence	$\sqrt{}$	
		of the Cry2Ab2 Protein Produced in E.		
		coli and Bt Against a Sensitive		
		Lepidopteran Species.		
7	В	An Acute Oral Toxicity Study in Mice	\checkmark	
		with Cry2Ab2 Protein.		
8	В	Assessment of the in vitro Digestibility	$\sqrt{}$	
		of the Cry2Ab2 Protein in Simulated		
		Gastric Fluid.		
9	В	Assessment of the in vitro Digestibility		
		of the Cry1A.105 Protein in Simulated		p · /
		Intestinal Fluid.		<u>.</u>
10	В	Assessment of the <i>in vitro</i> Digestibility	$\sqrt{}$	
		of the Cry2Ab2 Protein in Simulated	به د	
		Intestinal Fluid.		A 5 4 9 11
11	В	Bioinformatics Evaluation of the	√ ,	naz .
		Cryl A.105 Protein Utilizing the AD6,		
		TOXIN5, and ALLPEPTIDES	** 5	·
		Databases.	ş.	

Dr. S. Reilly Sept 28, 2006 Page 4 of 5

Volume	Category	Document	Hard Copy	.pdf file for Edocket
12	В	Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases.	V	
13 160	В	Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercial Com.	1	
14	В	Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry1A.105 Protein.	1	
15	В	Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry2Ab2 Protein.	7	
IG TRM	В	Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Against Major Insect Pests in United States, Puerto Rico and Argentina During 2003-2004 Seasons.	7	
17 Ew	В	Evaluation of Dietary Effects of Lyophilized Leaf Tissue from Corn MON 89034 in a Chronic Exposure Study with Collembola (Folsomia candida).	1	
18	В	Evaluation of Exposure to MON 89034 With the Cladoceran Daphnia magna: An Acute Static-renewal Test With Corn Pollen.	7	
19	В	Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate.	1	
20	В	Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (Apis mellifera L.).	7	
21	В	Evaluation of the Dietary Effect(s) of a Cryl A.105 Protein on Adult Honeybees (Apis mellifera L.).	1	en de de de de de

7 Stanlers

Dr. S. Reilly Sept 28, 2006 Page 5 of 5

Volume	Category	Document	Hard Copy	.pdf file for Edocket
22	В	Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae).	V	
23	В	Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae).	1	
24	В	Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae).	1	
25	В	Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae).	1	-
26	В	Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae).	7	
27	В	Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoptera: Ichneumonidae).	7	
28	В	Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain.	V	
29	В	Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins.	7	
30 E	∠o B	Endangered Species Risk Assessment for Corn MON 89034.	√	
31 IA	В	Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034.	√	

LIST OF SUBMITTED DOCUMENTS

Administra	tive Materials	RE
Volume 1.	Administrative Materials for the Application to Register the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3).	
	MRID Number	
Product Sur	<u>nmary</u>	R
Volume 2.	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant <i>Bacillus thuringiensis</i> Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.	
	MRID Number 469514-01	
Product Cha	aracterization_	£6
Volume 3.	Rice, J.F., B.J. Wolff, J.R, Groat, N.K. Scanlon, J.C. Jennings, and J.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	4.0
	MRID Number 07 aunafeal	
Volume 4.	Hartmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Technical Report MSL-20285.	Le
	MRID Number	

Monsanto Company

Transmittal Document

06-CR-172E-1

Page 2 of 8

Protein Safety

Volume 5.	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and <i>É. coli</i> -Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.	RE
	MRID Number	
Volume 6.	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in <i>E.Coli</i> and <i>Bt</i> Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.	RE
	MRID Number	
Volume 7.	Bonnette, K.L. 2006. An Acute Oral Toxicity Study in Mice with Cry2Ab2 Protein. Monsanto Study CRO-2005-049.	RE
	MRID Number	
Volume 8.	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the <i>in vitro</i> Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.	RE
	MRID Number	
Volume 9	Kapadia, S. and E.A. Rice. 2005. Assessment of the <i>in vitro</i> Digestibility of the Cry1A.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.	l E
	MRID Number	



Volume 10	Thorp, J.J. and M.E. Goley. 2006. Assessment of the <i>in vitro</i> Digestibility the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938.	of F
	MRID Number	
Volume 11.	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Evaluation of the Cry1A.105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.	LE
	MRID Number	
		RE
Volume 12.	McClain, J.S. and A. Silvanovich. 2006. Bioinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.	
	MRID Number	
Volume 13.	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Containing MON 89034, Control or Commercia Corn. Monsanto Study 05-01-50-13, Amended Report.	Zzý)
	MRID Number	
Insecticidal a	Activity	
Volume 14.	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry1A.105 Protein. Monsanto Technical Report MSL-20230.	.1
	MRID Number	٠.
	an or	
	t was expended to	

81.83

Volume 15.	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spe Activity of <i>Bacillus thuringiensis</i> Cry2Ab2 Protein. Mon Report MSL-20229.		L
	MRID Number	<u> </u>	
Volume 16.	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vaug Assessment of the Efficacy of Lepidopteran-protected Cormon 89597 Against Major Insect Pests in United States, Argentina During 2003-2004 Seasons. Monsanto Technic 05-RA-39-05.	rn MON 89034 and Puerto Rico and cal Report	ballo.
Ecotoxicolog	gy Studies		
Volume 17.	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyop from Corn MON 89034 in a Chronic Exposure Study with Collembola (<i>Folsomia candida</i>). Monsanto Technical Rep	l	
	MRID Number	· ·	
Volume 18.	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Expension 89034 with the Cladoceran <i>Daphnia magna</i> : An acute state corn pollen. Monsanto Study WL-2005-011.		
	MRID Number		
Volume 19.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Epotential Effects of Exposure to CryIA.105 Protein in an Atthe Earthworm in an Artificial Soil Substrate. Monsanto TMSL-20147.	Acute Study with	
	MRID Number		

(309)

Volume 20.	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Honeybee Larvae (<i>Apis mellifera</i> L.). Monsanto Study CA-2005-071.
	MRID Number
Volume 21.	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry1A.105 Protein on Adult Honeybees (<i>Apis mellifera</i> L.). Monsanto Study CA-2005-072.
	MRID Number
Volume 22.	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.
	MRID Number
Volume 23,	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, <i>Coleomegilla maculata</i> (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.
	MRID Number
Volume 24.	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry1A.105 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.
	MRID Number
	9.6 P

Volume 25.	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, <i>Orius insidiosus</i> (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.
	MRID Number
Volume 26.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry1A.105 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae) Monsanto Technical Report MSL-20149.
	MRID Number
Volume 27.	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, <i>Ichneumon promissorius</i> (Hymenoptera: Ichneumonidae). Monsanto Technical Report MSL-20148.
	MRID Number
Volume 28.	Gallagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dietary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dietary Study with Corn Grain. Monsanto Technical Report WL-2005-012.
	MRID Number
Volume 29.	Mueth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.
	MRID Number

Volume 30. Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394. MRID Number _____ Insect Resistance Management Volume 31. Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Corn, MON 89034. Monsanto Technical Report 06-RA-39-06. MRID Number ______S/-____ Company Official: Washat W. Bydowcom Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314) 694-3143 Company Name: Monsanto Company Company Contact: Russell P. Schneider, Ph.D.

Director, Regulatory Affairs

(202) 383-2866

Please read instructions on re	verse before completin	g form.	Form Ap	pproved. OME	B No. 2	070-0060. /	Approval Exp	ires 2-28-95
% EPA	Environmel Wa	United States ntal Protect shington, DC 2	ction Agend	;y		Registr Amend Other		OPP Idenlifier Number
	Applic	ation for P	esticide - S	Section I				
Company/Product Number File Symb	······································	LTL	2. EPA Produc		lly		3. Propose	d Classification
Company/Product (Name)	89034		PM#	-90		/	None	Restricted
5. Name and Address of Applicant (Inc.) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 Check if this is a new address	lude ZIP Code)		product is simila EPA Reg. No. Product Name	ar or ide <i>n</i> tical i	in com	position and	labeling to:	n 3(c)(3)(B)(i), my
		Sect	ion – II				<u></u>	
Amendment – Explain Resubmission in respo	onse to Agency letter da	ated		Final printed Agency lette "Me Too" Ap Other – Expl	er dated oplication	f on.	e to	
Explanation: Use additional page(s Application to Register the Plant- Material (Vector PV-ZMIR245) N	Incorporated Protect	ant <i>Bacillus th</i>	mringiensis Cry					
		Secti	on – III				***************************************	
1. Material This Product Will Be Pac	kaged In:							
Id-Resistant Packaging Yes* No * Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt.	No. per Container	Yes No If "Yes" Package wgt.	No. per Container		2. Type of C Meta Plas Glas Pap Othe (Specify)	al tic ss er	
Location of Net Contents Information	L	4. Size(s) Retai	I Container				el Directions	
Label Container		4. OLZOJOJ NOIZI	Various			n Label	accompanylr	
6. Manner in Which Label is Affixed to F	³ roduct	Lithograpi	h	Other				
		Paper glu Stenciled	ed					
			<u>on – IV</u>					
1. Contact Point (Complete items direct	ly below for identification	·	be confacted, if	necessary, to	proces:			
Name Russell P. Sch			Director, Regu	ılatory Affa	nirs	Teler	(202) 383	2 2 2
I certify that the statements I have I acknowledge that any knowingty both under applicable taw.	made on this form and	lement may be p					, , ,	Date Application Received ::(Stamped)
2. Signature Washell II	3 jul accom	3. Title	Regulatory A	Affairs Man	nager	, , ,	2 2	#
4. Typed Name Natalia N. Bogdanova	Tel. (314) 694-31		September 2					: >
EPA Form 8570-1 (Rev. 3-94)	Previous editions are	o obsolete	White - FPA	File Copy (or	cioinalì	Yelfow 1	 Applicant 	Conv

Monsanto Company 06-CR-I72E-1 Page 7 of 36



Natulia N. Bogdanova, D.V.M. Regulatory Affairs Manager (314)-694-3343 Monsania Company 1300 I (Eye) Street, NW Suite 450 East Washington, D.C. 20005-7211 Phone (202) 783-2460 Fax (202) 789-1819 http://www.mogsanto.com

September 28, 2006

Document Processing Desk (EUP)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attn: Dr. Sheryl Reilly, Team Leader 92

Subj: Application for the registration of the plant-incorporated protectant Bacillus thuringiensis

Cry1A.105 and Cry2Ab2 proteins produced in MON 89034

Dear Dr. Reilly:

Please find enclosed an application for the registration of the plant-incorporated protectant *Bacillus thuringiensis* (Bt) Cry1A.105 and Cry2Ab2 proteins and the genetic material necessary for their production in the corn product MON 89034. MON 89034 is a second-generation product that produces the Cry1A.105 and Cry2Ab2 proteins, which together control a wider spectrum of lepidopteran pests and offer an enhanced insect resistance management (IRM) tool compared to the current lepidopteran-protected corn product MON 810.

EPA established temporary exemptions from the requirement of a tolerance for the Cry1A.105 and Cry2Ab2 proteins and the genetic material for their production in corn (40 CFR §174.453 and 40 CFR §174.454, respectively). The results of the safety assessment demonstrated that the Cry1A.105 and Cry2Ab2 proteins as produced in MON 89034 will not pose any significant risk to human health or to the environment.

This application includes the following documents that, for purposes of placement in the Public Docket, have been classified as 'A' (non-confidential documents that can be released to the public), 'B' (data subject to the provisions of FIFRA Section 10(g) and therefore protected from disclosure to multinational or foreign pesticide producers), or 'C' (confidential business information). In addition, pdf files are included on a CD-ROM for placing documents classified as 'A' on the Edocket. The redacted version of the Administrative volume (pdf file) for the Edocket excludes the data matrix (agency internal use copy) and confidential attachment. Complete description of this submission by category is provided in the attachment to this letter.

* 66 5 50 80 Dr. S. Reilly Sept 28, 2006 Page 2 of 5

It is Monsanto's understanding that the following fee category and amount is appropriate based on the June 2, 2005 Federal Register notice for Pesticide fees and Decision Times:

- Fee category B81: Register new AI, temporary tolerance or exemption exists, SAP required;
- Fee Category Amount: \$315,000

Should you require any additional information regarding this submission please feel free to contact Dr. Russell Schneider in our Washington office (202-383-2866) or me directly (314-694-3143).

Sincerely,

Natalia N. Bogdanova, D.V.M.

cc: Mike Mendelsohn, EPA/OPP/BPPD Russell Schneider, Monsanto Monsanto Regulatory Files

Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

40 CM OMOSE, O.W., Vidaimigio	n, DC 20460. Do not send the form to this address.	ATA MATRIX				
Date: September 28, 2006				EPA Reg. No./	File Symbol: 524-X	XX Page I of 9
Applicant's/Registrant's Name & Monsanto Company, 800 N Ingredient Bacillus thuringit Identificr: MON-89034-3)	Address: Lindbergh Blvd., St. Louis, MO 63167 ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV	-ZMIR245) Necessary fo		ON 89034 tion in MON 89034	(OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Slaius	Note _
885.1100 885.1200 885.1500	Administrative Materiols for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis Cry1A. 105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3).		Monsanto Comp	any	O₩N	This Application
	Bogdanova, N.N. 2006. Human Health and Environmental Assessment of the Plant-Incorporated Protectant Bacillus thuringiensis Cry1A.105 and Cry2Ab2 Proteins Produced in Corn MON 89034.		Monsante Comp	any	OWN	This Application
885.1100 885.1200 885.1300 885.2100	Rice, J.F., B.J. Wolff, J.R, Groat, N.K. Scanlon, J.C. Jennings, and I.D. Masucci. 2006. Amended Report for MSL-20072: Molecular Analysis of Corn MON 89034. Monsanto Technical Report MSL-20311.	X	Monsanto Comp	any	own	This Application
885.1400 885.1500 885.2200 885.2400 885.2500	Hattmann, A.J., K.E. Niemeyer, and A. Silvanovich. 2006. Assessment of the Cry1A.105 and Cry2Ab2 Protein Levels in Tissues of Insect-Protected Corn MON 89034 Produced in 2005 U.S. Field Trials. Monsanto Teclmical Report MSL-20285.		Monsanto Come	pany	OWN	This Application
885.2100	Karunanandaa, K., J.J. Thorp, M.E. Goley, S.L. Levine, and A. Silvanovich. 2006. Characterization of the Cry2Ab2 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E. coli-Produced Cry2Ab2 Proteins. Monsanto Technical Report MSL-20071.		Monsanto Comp	natiy	OWN	This Application
Signature	to Butterna	<u></u>	Name and Title Natalia N. Bogdanova Regulatory Affairs Ma	, D.V.M.	Date September 28, 20	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.





Form Approved OMB No. 2070-0060

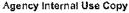
\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.					
	D/	ATA MATRIX				
Date: September 28, 2006				EPA Reg. I	No./File Symbol: 524-X	XX Page 2 of 9
	Lindbergh Blvd., St. Louis, MO 63167			. ,	MON 89034	
Ingredient <i>Bacillus thuringi</i> Identifter: MON-89Ø34-3)	iensis CryIA.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector PV	/-ZMIR245) Necessary (for their Proc	duetion in MON 89034	(OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.1100 885.2100 885.2200	Levine, S.L. and J. Uffman. 2006. Evaluation of the Functional Equivalence of the Cry2Ab2 Protein Produced in E. Coli and Bt Against a Sensitive Lepidopteran Species. Monsanto Technical Report MSL-20132.		Monsanto Com	pany	Own	This Application
885.3050 885.4150	Bonnette, K.L. 2006. An acute oral toxicity study in mice with Cry2Ab2 protein. Monsanto Study CRO-2005-049.		Monsanto Com	pany	OWN	This Application
885.3050	Kapadia, S.A. and E.A. Rice. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19931.		Monsanto Company		OWN	This Application
885.3050	Kapadia, S. and E.A. Rice. 2005. Assessment of the in vitro Digestibility of the Cry tA.105 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19930.		Monsanto Com	pany	OWN	This Application
885.3050	Thorp, J.J. and M.E. Gotey. 2006. Assessment of the in vitro Digestibility of the Cry2Ab2 Protein in Simulated Intestinal Fluid. Monsanto Technical Report MSL-19938		Monsanto Com	pany	OWN	This Application
885.1300 885.2100 885.2290	McClain, J.S. and A. Sitvanovich. 2006. Bioinformatics Evaluation of the Cryt A. 105 Protein Utilizing the AD6, TOXIN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20351.		Monsanto Com	pany	OWN	This Application
	onic and Pager various available. Submit only Pager var		Name and Title Natalia N. Bogdanova Regulatory Affairs M	•	Date September 28, 20	06

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.





⊗EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including lime for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the *lorm* to this address.

	finformation, including suggestions for reducing the burden, DC 20460. Do not send the form to this address.	ii to; Oilector, OPPE	. ппотпанов манаделевк от	usion (2137), O.S. Environmental Pr	diechon Agency,
	D/	ATA MATRIX			
Dale: September 28, 2006			EP	A Reg. No./File Symbol: 524-XXX	(Page 3 of 9
	. Lindbergh Blvd., St. Louis, MO 63167			oduct: MON 89034	
Ingredient Bacillus thurings Identifier: MON-89Ø34-3)	ensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	Malerial (Vector PV	V-ZMIR245) Necessary for the	ncir Production in MON 89034 (OI	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1300 885.2100 885.2200	McClain, J.S. and A. Silvanovich. 2006. Bjoinformatics Analysis of the Cry2Ab2 Protein Utilizing the AD6, TOXINS, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-20307.		Monsanio Company	OWN	This Application
	Davis, S.W. 2006. Comparison of Broiler Performance and Carcass Parameters When Fed Diets Comaining MON 89034, Control or Commercial Com. Monsanto Study 05-01-50-13, Amended Report.		Monsanto Company	OWN	This Application
885.4340	MacRau, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of <i>Bacillus thuringiensis</i> Cry1A.105 Protein. Monsanto Technical Report MSL- 20230.		Monsanto Company	OWN	This Application
885.4340	MacRae, T.C., C.R. Brown, and S.L. Levine. 2006. Spectrum of Insecticidal Activity of Bacillus thuringiensis Cry2Ab2 Protein. Monsanto Technical Report MSL- 20229.		Мопѕалю Сопірану	OWN	This Application
. V V V V V V V V V V V V V V V V V V V	Headrick, J.M., O. Heredia, I.O. Oyediran, and T.T. Vauglin. 2006. Assessment of the Efficacy of Lepidopteran-protected Corn MON 89034 and MON 89597 Againsi Major Insect Posts in United States, Puerto Rico and Argentina During 2003-2004 Seasons. Monsanto Technical Report 05-RA-39-05.		Monsanto Company	OWN	This Application
Signature	forh of Mylacion	272	Name and Title Natalia N. Bogdanova, D. Rogulatory Affairs Manag	V.M. Date September 28, 2006	7.

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, Do not send the form to this address.

401 M Street, S.W., Washington	n, DC 20460. Do not send the form to this address.			· · · · · · · · · · · · · · · · · · ·		
		ATA MATRIX		EPA Reg. No./File Symbo		
	Date: September 28, 20 0 6					Page 4 of 9
Applicant's/Registrant's Name &						
Monsanto Company, 800 N	. Lindbergh Blvd., St. Louis, MO 63167			roduct: MON 89034		
Ingredient Bacillus thuring Identificr: MON-89Ø34-3)	rensis Cryl A.105 and Cry2Ab2 Proteins and the Genetic	Material (Vector P	V-ZMIR245) Neccssary fo	r their Production in MC	ON 89034 (OEC	CD Unique
Guideline Reference Number	Guideline Study Name	MRIO Number	Submitter	Sta	llus	Note
885.4340	Teixeira, D. 2006. Evaluation of Dietary Effects of Lyophilized Leaf fissue from Com MON 89034 in a Chronic Exposure Study with Collembola (Folsomia candida). Monsanto Technical Report MSL-20169.		Monsanto Coпгра	ny OV	<u>vn</u> t	his Application
885.4340	Palmer, S.J. and H.O. Krueger. 2006. Evaluation of Exposure to MON 89034 with the Cladoceran Daphnia magna: An acute static-renewal test with compollen. Monsanto Study W1-2005-011.		Monsanto Compa	ny OV	VN T	his Application
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to CrylA.105 Protein in an Acute Study with the Earthworm in an Artificial Soil Substrate. Monsanto Technical Report MSL-20147.		Monsanto Compa	nyOV	T NW	his Application
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a Cry IA.105 Protein on Honeybee Larvae (Apis mellifera L.). Monsanto Study CA-2005-071.		Monsanto Compa	ny OV	VN T	his Application
885.4380	Richards, K.B. 2006. Evaluation of the Dietary Effect(s) of a CrylA.105 Protein on Adult Honeybees (Apis mellifera L.). Monsanto Study CA-2005-072		Monsanto Compa	ny OV	VN T	his Application
885.4346	Paradise, M.S. 2006. Evaluation of Potential Dictary Effects of Cryl A. 105 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20150.		Monsanto Compa	ny Ov	T NW	his Application
Signature Material of Byelowin			Name and Title Natalia N. Bogdanova, l Regulatory Affairs Man		er 28, 2006	

EPA Form 8570-35 (9-27) Electronic and Paper versions available. Submit only Paper version.



SEPA

Form Approved OMB No. 2070-0060 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D,	ATA MATRIX				
Dale: September 28, 2006				EPA Reg. No	o./File Symbol: 524->	XX Page 5 of 9
	Address: . Lindbergh Blvd., St. Louis, MO 63167 ensis CryIA.105 and Cry2Ab2 Proteins and the Genetic	Malcrial (Vector PV		· ·	AON 89034 action in MON 89034	(OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter		Status	Note
885.4340	Paradise, M.S. 2006. Evaluation of Potential Dietary Effects of Cry2Ab2 Protein on the Ladybird Beetle, Coleomegilla maculata (Coleoptera: Coccinellidae). Monsanto Technical Report MSL-20151.		Monsanto Comp	any	OWN	This Application
885.4340	Teixeira, D. 2006. Evaluation of Potential Dietary Effects of Cryl A. 105 Protein on Minute Pirate Bugs, Orius iustidiosus (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20170.		Monsante Company		OWN	This Application
885.4340	Teixeira, D. 2006. Evaluation of Porential Dietary Effects of Cry2Ab2 Protein on Minute Pirate Bugs, Orius insidiosus (Hemiptera: Anthocoridae). Monsanto Technical Report MSL-20171.		Monsanto Company		OWN	This Application
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krueger. 2006. Evaluation of Potential Effects of Exposure to Cryl A.105 Prorein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (Hymenoprera: tehneumonidae). Monsanto Technical Report MSL-20149.		Monsanto Company		OWN	This Application
885.4340	Sindermann, A.B., J.R. Porch, and H.O. Krneger. 2006. Evaluation of Potential Effects of Exposure to Cry2Ab2 Protein in an Acute Study with the Parasitic Wasp, Ichneumon promissorius (htymenoprera: Ichneumonidae). Monsanto Technical Report MSL-20148.		Monsanto Comp	any	о w и	This Application
Signature	lah at Bylance		Name and Title Natalia N. Bogdanova, Regulatory Affairs Ma		Date September 28, 20	06

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



Form Approved OMB No. 2070-0060

⊕EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

· · · · · · · · · · · · · · · · · · ·	D	ATA MATRIX			
Date: September 28, 2006			EPA Re	g. No./File Symbol: 524-X	XX Page 6 of 9
	. Lindbergh Blvd., St. Louis, MO 63167		Product		
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	ensis Cry I A. 105 and Cry 2 Ab 2 Proteins and the Genetic	Material (Vector P)	V-ZM1R245) Necessary for their I	Production in MON 89034	(OECD Unique
Guideline Reference Number	Guìdeline Study Name	MRID Number	Submitter	Status	Note
885.4050	Galtagher, S.P. and J.B. Beavers. 2006. Evaluation of Potential Dictary Effects of MON 89034 with the Northern Bobwhite: an Eight-day Dictary Study with Corn Grain. Monsanto Technical Report WL-2005-012.		Monsanto Company	OWN	This Application
885.5200	Mucth, M., T. Curran, J. Warren, S. Dubelman, M. Glaspie, J. Murphy, S. Levine, J. Holtmeyer, and C. Jiang. 2006. Aerobic Soil Degradation of the Purified Cry2Ab2 and Cry1A.105 Proteins. Monsanto Technical Report MSL-20174.		Monsanto Company	OWN	This Application
	Huesing, J.E., J.J. Duan, and S.L. Levine. 2006. Endangered Species Risk Assessment for Corn MON 89034. Monsanto Technical Report MSL0020394.		Monsanto Company	OWN	This Application
	Head, G. 2006. Insect Resistance Management Plan for Second Generation Lepidopteran-Protected Com, MON 89034. Monsanto Technical Report 06-RA-39-06.		Monsanto Company	OWN	This Application
Signature	al A Byelan		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 28, 200	06

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



Form Approved OMB No. 2070-0060

\$EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 40 t M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	D	ATA MATRIX			
Date: September 28, 2006		EPA	EPA Reg. No./File Symbol: 524-XXX Page 7 of 9		
Applicant's/Registrant's Name &					
	. Lindbergh Blvd., St. Louis, MO 63167		luct: MON 89034		
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	riensis Cry1A.105 and Cry2Ab2 Proteins and the Geneti	c Material (Vector I	V-ZMIR245) Necessary for the	eir Production in MON 89034 (C	ECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Goenz, B., T. Ganguly, J. Lee, T. Lee, and E.A. Rice. 2005. Characterization of the CrytA.105 Protein Purified from the Corn Grain of MON 89034 and Comparison of the Physicochemical and Functional Properties of the Plant-Produced and E.colf-Produced CrytA.105 Proteins. Monsanto Technical Report MSL-				
885.2100	19960,	46694604	Monsanto Company	OWN	
885.3050 885.4150	Bonnette, K.L. 2005. An Acute Oral Toxicity Study in Mice with CrytA.105 Protein. Monsanto Study CRO-2005-050.	46694603	Monsanto Company	OWN	<u></u>
885.3050	Kapadia, S.A. and E.A. Ricc. 2005. Assessment of the invitro Digestibility of the Cryt A. 105 Protein in Simulated Gastric Fluid. Monsanto Technical Report MSL-19929.	46694606	Monsanto Company	OWN	
885.3050	Gotey, M.E. and J.J. Thorp. 2005. Immunodetection of Cry2Ab2 and Cry1A. 105 Proteins in Corn Grain from MON 89034 Following Heat Treatment. Monsanto Technical Report MSL-19899.	46694607	Monsanto Company	OWN	
885.4340	MacRac, T.C., C.R. Brown, S.L. Levine. 2005. Evaluation of the Potential for Interactions Between the Baciffus Thuringiensis Proteins CrytA.105 and Cry2Ab2. Monsanto Technical Report MSL-19859.	46694602	Monsanto Company	OWN	
Signature Maked M. Byokovovo		Name and Title Natalia N. Bogdanova, D.V Regulatory Affairs Manage		•	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	DA	ATA MATRIX			
Date: September 28, 2006	E	EPA Reg. No./File Symbol: 524-XXX Page 8 c			
Applicant's/Registrant's Name & Monsanto Company, 800 N		Product: MON 89034			
Ingredient Bacillus thuring Identificr: MON-89034-3)	riensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic	: Material (Vector F	V-ZMlR245) Necessary for	their Froduction in MON 89034 (C	DECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.J. and H.O. Krneger. 2000. Insect Protection Protein 2: An Acuse Toxicity Study With the Earthworm in an Artificiat Soil Substrate. Monsanto Technical Report MSL-16177	450863 t3	Monsanto Compan	y OWN	
885.4380	Maggi, V.L. 2000. Evaluation of dietary effect(s) of purified Bacillus thuringiensis Cry2Ab2 protein on honey bee tarvae. Monsamo Technical Report MSL-1696 t.	45337102	Monsanto Compan	y OWN	
885.4380	Maggi, V.L. 2000. Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (Apis mellifera L.). Monsanto Technicat Report MSL-16176.	45086308	Monsanio Compan	y OWN	
885.2300	Dudin, Y.A and P. Chinnadurai. 2005. Qualitative Detection Method for the Cry2Ab2 Protein in Corn Leaf and Seed of MON 89034 and MON 89597. Monsanto Technical Report 05-RA-39-04.	46694503	Monsanto Compan	yOWN	
Signature Bylows			Name and Title Natalia N. Bogdanova, D Regulatory Affairs Mana	1 -	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



©EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Oivision (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

	ַלַם	ATA MATRIX			
Date: Seplember 28, 2006			EPA I	Reg. No./File Symbol: 524-XXX	Page 9 of 9
Applicants/Registrants Name &	Address: Lindbergh Blvd., St. Louis, MO 63167	,	Dd.	ict: MON 89034	
	iensis Cry IA.105 and Cry2Ab2 Proteins and the Genetic	c Material (Vector F	Produ V-ZM1R245) Necessary for the		CD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1300 885.2100	Rice, J.F., B.J. Wolff, J.C. Jennings, and J.D. Masucci. 2005. Summary of Southern Blot Analysis of MON 89034 and MON 89597 Corn. Mousanto Technical Report MSL-20068	46694501	Monsanto Company	OWN	
885.1300 885.2100 885.2200	McCoy, R.L. and A. Silvanovielt. 2005. Bioinformatics Analysis of the CrytA. 105 Protein Utilizing the AD5, TOXtN5, and ALLPEPTIDES Databases. Monsanto Technical Report MSL-19686.	46694605	Monsanto Company	OWN	
885.4340	Teixeira, D. 2000. Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (Folsonia candida), Amended report. Monsanto Technical Report MSL-16174.	45086314	Monsanto Company	OWN	
885.4340	Palmer, S. and H. Krueger. 2000. Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (Nasonia vitripennis). Monsanto Technical Report MSL-16173.	45086310	Monsanto Company	OWN	
885.1100 885.2100	Bogdanova, N.N. 2005. Structural and Functional Similarity of the Cry1A.105 Protein to Cry1A Class of Bacillus thuringiensis Proteins. Monsanto Technical Report 05-RA-62-01.	4669460 i	Monsanto Company	OWN	
Signature of Figure 1			Name and Title Natalia N. Bogdanova, D.V.I Regulatory Affairs Manager	Date September 28, 2006	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.



Form Approved OMB No. 2070-0060

ŞEPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the pecessary forms. Send comments regarding the burden estimate or any

	special review activilies, including time for read if information, including suggestions for reducin				
	n, DC 20460. Do not send the form to this addi		-		
		DATE IN THE			
Date: September 28, 2006				No./File Symbol: 524-X	XX Page lof 9
Applicant's/Registrant's Name					······································
	I. Lindbergh Blvd., St. Louis, MO 63167			MON 89034	<u>.</u>
Ingredient Bacillus thuring Identifier: MON-89Ø34-3)	giensis Cry I A. 105 and Cry2Ab2 Proteins and	the Genetic Material (Vector PV-	-ZMIR245) Necessary for their Pr	oduction in MON 89034	4 (OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
Signature	al I Bylan		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 28, 20	

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.





\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

response for reregistration and so other aspect of this collection of	ice: The public reporting burden for this co special review activities, including time for information, including suggestions for redu , DC 20460. Do not send the form to this a	reading the instructions and completinucing the burden to: Director, OPPE In	g the necessary forms. Send comr	nents regarding the burn	ien estimale or any
		DATA MATRIX			
Date: September 28, 2006			EPA Reg.	No./File Symbol: 524-X	XX Page 2 of 9
	Lindbergh Blvd., St. Louis, MO 631		Product: MON 89034		
Ingredient Bacillus thurrings Identifier: MON-89Ø34-3)	iensis Cryl A.105 and Cry2Ab2 Proteins a	and the Genetic Material (Vector PV-	ZMIR245) Necessary for their Pro	duction in MON 89034	I (OECD Unique
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	This Application
			Monsante Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
		•	Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
Signature Make.	h or Bylan	7-22	Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 28, 20	This Application

EPA Form 8570-35 (9-97] Electronic and Paper versions available. Submit only Paper version.





\$EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

		DATA MATRIX			······	
Date: September 28, 2006			FPA Ren J	No./File Symbol; 524-X	(XX Page 3 of 9	
Applicant's/Registrant's Name			CITCOG	1031 10 Oyanbor, 52 1 3	1.130201	
Aonsanto Company, 800 l	N. Lindbergh Blvd., St. Louis, MO 6316	57		Product: MON 89034		
ngredient <i>Bacillus thu</i> rin dennifier: MON-89Ø34-3)	ngiensis CrytA.105 and Cry2Ab2 Proteins at	nd the Genetic Material (Vector PV-2	(MIR245) Necessary for their Pro	duction in MON 89034	4 (OECD Unique	
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note	
		-	Monsanto Company	OWN	This Application	
			Monsanto Company	OWN	This Application	
			Monsanto Company	OWN	This Application	
		MANAGE STATE OF TH	Monsanto Company	OWN	This Application	
			Monsanto Company	OWN	This Applicatio	
Signature	al or Bylan		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 28, 20		

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.





⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Date: September 28, 2006 EPA Reg. No./File Symbol: 524-XXX Page 4 of 9 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Bricillus thuringieusis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Ingredient Identifier: MON-89Ø34-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note OWN This Application Monsanto Company OWN Monsanto Company This Application Monsanto Company OWN This Application Monsanto Company OWN This Application Monsanto Company OWN This Application OWN Monsanto Contpany This Application Date Signature Name and Title Untal of Bydana September 28, 2006 Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available, Submit only Paper version.





Monsanto Company

♦ EPA

Form Approved OMB No. 2070-0060
TES ENVIRONMENTAL PROTECTION AGENCY

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

		DATA MATRIX			
Date: September 28, 2006			EPA Reg.	No./File Symbol: 524-)	XX Page 5 of 9
Applicant's/Registrant's Name &	Address:				
Monsanto Company, 800 N	Lindbergh Blvd., St. Louis, MO 63167			MON 89034	
ngredient Bacillus thuring dentifier: MON-89Ø34-3)	rensis Cry1A.105 and Cry2Ab2 Proteins and t	he Genetic Material (Vector PV-2	ZMIR245) Necessary for their Pro	oduction in MON 8903	4 (OECD Unique
Suideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsauto Company	DWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanto Company	OWN	This Application
			Monsanio Company	OWN	This Application
ignature	al M. Bystan		Name and Title Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager	Date September 28, 20	906

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.





⊕ EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Date: September 28, 2006 EPA Reg. No./Fite Symbol: 524-XXX Page 6 of 9 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Bacillus thuringiensis Cry 1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3) Guideline Reference Number **Guideline Study Name** MRtD Number Submitter Status Note Monsanto Company OWN This Application Monsanto Company OWN This Application Monsanto Company OWN This Application Monsanto Company OWN This Application white w. Byelacon Signature Date Name and Title September 28, 2006 Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any

other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Date: September 28, 2006 EPA Reg. No./File Symbol: 524-XXX Page 7 of 9 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Ingredient Bacillus thurringiensis Cry1A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89@34-3) Guideline Reference Number Guideline Study Name MRID Number Submitter Status Note Monsanto Company OWN. Monsanto Company OWN OWN Monsanto Company Mousanto Company OWN Monsanto Company OWN wonder of Byolanon Signature Date Name and Title September 28, 2006 Natatia N. Bogdanova, D.V.M. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy



⊕ EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. On not send the form to this address.

DATA MATRIX Date: September 28, 2006 EPA Reg. No./File Symbol: 524-XXX Page 8 of 9 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Bacillus thuringieusis Cry A, 105 and Cry Ab 2 Proteins and the Genetic Meterial (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Ingredient Identifier: MON-89Ø34-3) Guideline Study Name Guideline Reference Number MRID Number Submitter Status Note Monsanto Company OWN Monsanto Company OWN Monsanto Company OWN Monsonto Company OWN Signature Date Name and Title datal H. Bydanon September 28, 2006 Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Public File Copy

Form Approved OMB No. 2070-0060



⊕EPA

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Oirector, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address. DATA MATRIX Date: September 28, 2006 EPA Reg. No./File Symbol: 524-XXX Page 9 of 9 Applicant's/Registrant's Name & Address: Monsanto Company, 800 N. Lindbergh Blvd., St. Louis, MO 63167 Product: MON 89034 Baciflus thuringiensis Cry (A.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Ingredient Identifier: MON-89Ø34-3) MRID Number Guideline Reference Number Guideline Study Name Submitter Status Note Monsanto Contpany OWN Monsanto Company OWN Monsanto Company OWN Monsanto Company OWN Monsanto Company OWN Signature Date Name and Title shed of Bolowan September 28, 2006 Natalia N. Bogdanova, D.V.M.

EPA Form 8570-35 (9-97) Etectronic and Paper versions available. Submit only Paper version.

Public File Copy



Monsanto Company

Regulatory Affairs Manager

SECTION II

SUMMARY OF THE APPLICATION

A health and environmental assessment of the Cry1A.105 and Cry2Ab2 proteins produced in MON 89034, as well as the product benefits, are provided in Volume 2 of this application. Studies supporting product characterization and protein safety are provided in Volumes 3 through 13, along with additional studies and information cited in the data matrix. Insecticidal activity and ecotoxicology studies are presented in Volumes 14 though 29 along with additional studies and information cited in the data matrix. An endangered species risk assessment and an insect resistance management (IRM) plan are provided in Volumes 30 and 31, respectively.

Monsanto Company 06-CR-172E-1 Page 28 of 36



SECTION III

PRODUCT LABEL

The subject of this application is for the *Bacillus thuringiensis* Cry1A.105 and Cry2Ab2 proteins and the genetic material (PV-ZMIR245) necessary for their production in all corn containing MON 89034, including field corn, popcorn, and sweet corn. A full and unrestricted FIFRA section 3 registration is being sought to support commercialization of this product. Two copies of the proposed label for MON 89034 are attached.

Monsanio Company 06-CR-172E-1 Page 29 of 36



Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn (OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 com......0.002 – 0.0056%

Percentage (wt/wt) on a dry weight basis whole plant (forage).

CAUTION

KEEP OUT OF REACH OF CHILDREN

NET CONTENTS____

EPA Registration No. 524-xxx

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Information regarding commercial production to be included in the Grower Guide for Cotton and Non-Cotton Growing Areas.



Plant-Incorporated Protectant Label

MON 89034

Lepidopteran-Protected Corn (OECD Unique Identifier: MON-89Ø34-3)

Active Ingredients:
Bacillus thuringiensis Cry1A.105 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89034 com0.002 – 0.0056%
Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production (vector PV-ZMIR245) in event MON 89304 corn0.0015 – 0.0055%
Percentage (wt/wt) on a dry weight basis whole plant (forage).
CAUTION
KEEP OUT OF REACH OF CHILDREN
NET CONTENTS
EPA Registration No. 524-xxx
ED 4 E-4-11-1 4 M - 204 M O 000

EPA Establishment No. 524-MO-002

Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this seed in any manner inconsistent with this labeling.

Information regarding commercial production to be included in the Grower Guide for Cotton and Non-Cotton Growing Areas.

337

SECTION IV

PRODUCT ANALYSIS

Studies and volumes listed in the data matrix included in this application describe the a) health and environmental assessment of MON 89034, b) the molecular identity of MON 89034, and c) levels of the Cry1A.105 and Cry2Ab2 proteins produced in tissues of MON 89034.

Monsanto Company 06-CR-172E-1 Page 32 of 36



SECTION V

RESIDUE DATA

On 17 July 2006, EPA established a time-limited exemption from the requirement of a tolerance for the plant-incorporated protectants: *Bacillus thuringiensis* Cry1A.105 protein and *Bacillus thuringiensis* Cry2Ab2 protein, and the genetic material necessary for their production in corn (40 CFR §174.453 and 40 CFR §174.454, respectively). Therefore, residue data are not required for this product.

Monsanio Company 06-CR-172E-1 Page 33 of 36



SECTION VI

NONTARGET ORGANISM DATA

Studies have been conducted by Monsanto to characterize the potential hazards to nontarget organisms (NTOs) as a result of exposure to the Cry1A.105 and Cry2Ab2 proteins, and are presented in this application. Reports for relevant studies previously submitted to EPA are referenced by MRID in the data matrix. The environmental assessment of the Cry1A.105 and Cry2Ab2 proteins produced in MON 89034 is described in Volume 2 of this application.

(340)

Monsanto Company 06-CR-172E-1 Page 34 of 36

SECTION VII

TOXICOLOGY DATA

Studies conducted to assess the potential toxicity and allergenicity of the Cry1A.105 and Cry2Ab2 proteins have previously been submitted to EPA and are referenced by MRID in the data matrix. Studies were conducted demonstrating the equivalence of the Cry1A.105 and Cry2Ab2 proteins used as test material in these potential toxicity and allergenicity studies, to the Cry1A.105 and Cry2Ab2 proteins produced in MON 89034, respectfully. The study demonstrating functional equivalence of the *E. coli*- and plant-produced Cry1A.105 protein is referenced by MRID number 46694604 in the data matrix, and the study demonstrating functional equivalence of the E. coli- and plant-produced Cry2Ab2 protein is included as Volume 5 of this application.

(341)

Monsanto Company 06-CR-172E-1 Page 35 of 36

SECTION VIII

EFFICACY DATA

Data demonstrating the efficacy of the Cry1A.105 and Cry2Ab2 proteins produced in MON 89034 are presented in this application. The spectrum of insecticidal activity of the Cry1A.105 and Cry2Ab2 proteins are presented in Volumes 14 and 15, respectively, and the efficacy of MON 89034 against major insect pests in U.S. is presented in Volume 16 of this application. The proposed IRM plan for MON 89034 is provided in Volume 31 of this application.

(

	OFFICIAL		FILE SYMBOL 524- HEGISTRATION	LTL NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE	SUBMIT	TED BY (.)	
SUBMITTED	APPLICANT	BASIC SUPPLIER	Do Not Write Comment
9/29/06			Formula, or Parts of Form
			,
			on This Envelope
			in a proper parties
			NOTE
	ļ		It shall be unlawful—for any person to use for his
			or to reveal, other than to the Secretary, or officials
\			the United States Department of Agriculture or other F
			or to the courts in response to a subpoena, or to pl
		**************************************	emergencies to pharamacists and other qualified per
		ļ	the preparation of antidotes, in accordance with su
			the Secretary may prescribe, any information relative
<u></u>			products acquired by authority of Section 4 of the "Fer
			Fungicide, and Rodenticide Act."

Do Not Write Comments. Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful-for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies. or to the courts in response to a subpoena, or to physicians, and in emergencies to pharamacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

EPA Registration File No. 524-575 (Vol. 1).
Page is not included in this copy.
Pages 344 through 346 are not included in this copy
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
X The product confidential statement of formula.
Information about a pending registration action.
FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
Enforcement sensitive information.
Attorney-Client Privilege.
Claimed Confidential by submitter upon submission to the Agency.
Internal Deliberative Information.
* The information not included is generally considered confidential by prod registrants. If you have any questions, please contact the individual who prepared the response to your request.

.

VOLUME 1

Administrative Materials for the Application to Register the Plant-Incorporated Protectant, Bacillus thuringiensis CryIA.105 and Cry2Ab2 Proteins and the Genetic Material (Vector PV-ZMIR245) Necessary for their Production in MON 89034 (OECD Unique Identifier: MON-89Ø34-3)

EPA File 524 - XXX

CONFIDENTIAL ATTACHMENT

AUTHOR

Natalia N. Bogdanova, D.V.M. Regulatory Affairs Manager

SUBMISSION DATE

September 28, 2006

SUBMITTING REGISTRANT

Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167

MONSANTO REFERENCE No.

06-CR-172E-1

347)

Dagag	through and individed in this case.
rages	through are not included in this copy.
	aterial not included contains the following type of mation:
	Identity of product inert ingredients.
	Identity of product impurities.
	Description of the product manufacturing process.
	Description of quality control procedures.
	Identity of the source of product ingredients.
	Sales or other commercial/financial information.
	A draft product label.
	The product confidential statement of formula.
	Information about a pending registration action.
x	_ FIFRA registration data.
	The document is a duplicate of page(s)
	The document is not responsive to the request.
	Proprietary information pertaining to the chemical composition of an inert ingredient provided by the sou of the ingredient.
	Enforcement sensitive information.
	Attorney-Client Privilege.
	Claimed Confidential by submitter upon submission to th Agency.
-	Internal Deliberative Information.